Supreme Court, U.S.
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No.

In the Supreme Court of the United States

OCTOBER TERM, 1998

FOOD AND DRUG ADMINISTRATION, ET AL., PETITIONER

v.

BROWN AND WILLIAMSON TOBACCO CORP., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

APPENDIX TO PETITION FOR A WRIT OF CERTIORARI

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APPENDIX A

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

Nos. 97-1604, 97-1581, 97-1606,
97-1614 and 97-1605

BROWN & WILLIAMSON TOBACCO CORPORATION;
LORILLARD TOBACCO COMPANY; PHILIP MORRIS,
INCORPORATED; RJ REYNOLDS TOBACCO COMPANY,
PLAINTIFFS-APPELLANTS

AND

COYNE BEAHM, INCORPORATED;
LIGGETT GROUP, INCORPORATED, PLAINTIFFS

v.

FOOD & DRUG ADMINISTRATION;
DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD AND
DRUGS, DEFENDANTS-APPELLEES

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ASSOCIATION; AMERICAN SOCIETY OF ADDICTION
MEDICINE; THE HMO GROUP;
NATIONAL ASSOCIATION OF ELEMENTARY SCHOOL
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ACME RETAIL, INCORPORATED; UNITED STATES
TOBACCO COMPANY; CONWOOD COMPANY, LP;
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TOBACCO COMPANY; SWISHER INTERNATIONAL,
INCORPORATED; CENTRAL CAROLINA GROCERS,

INCORPORATED; J.T. DAVENPORT, INCORPORATED;
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[Argued: June 9, 1998
Decided: Aug. 14, 1998]

Before: WIDENER, Circuit Judge, HALL, Senior Circuit Judge, and MICHAEL, Senior United States District Judge for the Western District of Virginia, sitting by designation.

Reversed by published opinion. Judge WIDENER wrote the opinion, in which Senior Judge MICHAEL joined. Senior Judge K.K. HALL wrote a dissenting opinion.

WIDENER, Circuit Judge:

On August 28, 1996, the Food and Drug Administration (FDA) published a final rule entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." 61 Fed.Reg. 44,396 (1996) (to be codified at 21 C.F.R. pt. 801, *et al.*). In general, this rule set out regulations restricting the sale and distribution of cigarettes and smokeless tobacco (collectively referred to as tobacco products) to minors and limiting the advertising and promotion of tobacco products. Plaintiffs (cigarette and smokeless tobacco manufacturers, convenience store retailers, and advertisers) filed these consolidated actions in federal district court, challenging the FDA's jurisdiction over tobacco products and seeking declaratory and injunctive relief.[1] Plaintiffs then filed a motion for summary judgment in the district court, alleging that, as a matter of law: (1) Congress has withheld from the FDA the jurisdiction to regulate tobacco products as marketed by plaintiffs; and (2) the Federal Food, Drug, and Cosmetic Act (Act) does not permit the FDA to regulate tobacco products either as drugs or as devices. In denying plaintiffs' motion for summary judgment in part and granting the motion in part, the district court held that Congress did

[1] When the complaint was filed on August 10, 1995, the FDA had only issued a Notice of Proposed Rulemaking. 60 Fed.Reg. 41,314 (1995). Following a comment period, the FDA adopted the proposed rule in modified form. 61 Fed.Reg. 44,396 (1996). Unless noted otherwise, all references in this opinion are to the final version of the rule published in the Federal Register on August 28, 1996. Where italics appear here within a quotation, they have been added for emphasis unless otherwise indicated.

not "[intend] to withhold from FDA" the jurisdiction to regulate tobacco products. *Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1388 (M.D.N.C.1997). The district court also concluded that the FDA had authority to regulate tobacco products under the device provision of the Act, but disapproved the FDA's restrictions on advertising as inconsistent with its statutory authority. *Coyne Beahm*, 966 F. Supp. at 1393-1400. Finally, the district court stayed implementation of the majority of the FDA's regulations pending appeal.[2] *Coyne Beahm*, 966 F. Supp. at 1400-01. The district court certified its order for immediate interlocutory appeal pursuant to 28 U.S.C. § 1292(b), *Coyne Beahm*, 966 F. Supp. at 1401, and by order dated May 13, 1997, this court granted the § 1292(b) petitions for immediate appeal filed by two of the plaintiff groups and the FDA. In addition, the FDA had filed its Notice of Appeal dated May 2, 1997 from the partial injunction granted by the district court. Jurisdiction over the consolidated appeals is proper in this court under 28 U.S.C. §§ 1292(a)(1) and 1292(b).

Because this case arises from a motion for summary judgment, we review the judgment of the district court *de novo*. *Myers v. Finkle*, 950 F.2d 165, 167 (4th Cir.1991). For purposes of these appeals, plaintiffs do not dispute the factual findings of the FDA. Based on our review of the record and the relevant legal authorities, we are of opinion that the FDA lacks jurisdiction

[2] The district court left in place the FDA's proof of age requirement for tobacco sales and the restrictions on sales to persons under age 18, which had already gone into effect. *Coyne Beahm*, 966 F. Supp. at 1400. However, all 50 States have already banned the sale of tobacco to minors under state law. See 61 Fed. Reg. at 44,419 (citing a joint letter from 25 state attorneys general and other comments submitted to the FDA).

to regulate tobacco products. For the reasons set forth below, all of the FDA's August 28, 1996 regulations of tobacco products are thus invalid. Accordingly, we reverse the judgment of the district court.

I. *FDA's Asserted Basis for Jurisdiction*

The FDA[3] has authority to regulate products only if they fall within one of the categories defined by Congress in the Act.[4] In the jurisdictional determination attached to its August 28, 1996 regulations, the FDA asserted jurisdiction over tobacco products under the drug[5] and device[6] definitions in the Act. 61 Fed. Reg. at 44,628. According to the FDA, tobacco products fit within these definitions because they are "intended to affect the structure or any function of the

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[3] On most occasions, the Act refers to the authority of the Secretary of the Department Health and Human Services (HHS) to take certain actions. However, the Secretary acts through the Commissioner of Food and Drugs. 21 U.S.C. § 393(d)(2). For simplicity, we will refer to any legislative delegation as if made directly to the FDA.

[4] The categories of products subject to regulation by the FDA are food, drugs, devices, and cosmetics. 21 U.S.C. § 321.

[5] The Act defines "drug" in pertinent part as "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1)(C).

[6] In relevant part, "device" is defined as an article which is:

> intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes

21 U.S.C. § 321(h)(3).

body." More specifically, the FDA concluded that tobacco products are "combination products consisting of nicotine, a drug that causes addiction and other significant pharmacological effects on the human body, and device components that deliver nicotine to the body."[7] 61 Fed. Reg. at 44,628, 44,649-650. Based on its classification of tobacco products as combination products, the FDA claimed that it could exercise its discretion in deciding whether the drug provisions or device provisions of the Act should apply. 61 Fed. Reg. at 44,400. Although finding that tobacco products function primarily as drugs, 61 Fed. Reg. at 45,209-218, the FDA concluded that tobacco products are most properly regulated under the device provisions of the Act, in particular the restricted devices section, 21 U.S.C. § 360j(e).[8] 61 Fed. Reg. at 44,400. The FDA's

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[7] A combination product is described as a product that contains a combination of a drug, device, or biological product. 21 U.S.C. § 353(g). Neither party contends that tobacco products contain any "biological product," as that term is used in the Act. See 42 U.S.C. § 262(I) (defining a biological product as a "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings").

[8] Section 360j(e) provides in relevant part:

> (1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—
>
> . . .
>
> (B) upon such other conditions as the Secretary may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.

jurisdictional determination encompasses over 600 pages in the Federal Register; however, its basic premise can be fairly summarized in one sentence. That is, the FDA asserted jurisdiction over tobacco products based on its conclusion that tobacco products fit within the literal definitions of drug and device as set forth in the Act. In short, the FDA's inquiry began and ended with the definitions section of the Act.

We are of opinion that the FDA's limited, mechanistic inquiry is insufficient to determine Congress' intent. Therefore, as directed by *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S. Ct. 2778, 81 L.Ed.2d 694 (1984), we employ the traditional tools of statutory construction to ascertain congressional intent regarding whether the FDA has authority to regulate tobacco products.

II. *Jurisdictional Analysis*

We begin with the basic proposition that agency power is "not the power to make law. Rather, it is 'the power to adopt regulations to carry into effect the will of Congress as expressed by the statute.'" *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 213-14, 96 S. Ct. 1375, 47 L.Ed.2d 668 (1976) (quoting *Manhattan Gen. Equip. Co. v. Commission*, 297 U.S. 129, 134, 56 S. Ct. 397, 80 L.Ed. 528 (1936)). Thus, our initial inquiry is whether Congress intended to delegate to the FDA authority to regulate tobacco products as "customarily marketed."[9]

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21 U.S.C. § 360j(e).

[9] Plaintiffs use the term "customarily marketed" in their briefs to indicate tobacco products marketed with customary claims such as smoking pleasure as opposed to tobacco products

The district court framed the issue as "whether Congress has evidenced its clear intent to *withhold* from FDA jurisdiction to regulate tobacco products as customarily marketed." *Coyne Beahm*, 966 F. Supp. at 1380. However, we are of opinion that the issue is correctly framed as whether Congress intended to *delegate* such jurisdiction to the FDA. See *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208, 109 S. Ct. 468, 102 L.Ed.2d 493 (1988) (stating that "[i]t is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress"); *INS v. Chadha*, 462 U.S. 919, 953 n. 16, 955 n. 19, 103 S. Ct. 2764, 77 L.Ed.2d 317 (1983) (providing that agency action "is always subject to check by the terms of the legislation that authorized it; and if that authority is exceeded it is open to judicial review" and "Congress ultimately controls administrative agencies in the legislation that creates them"). This fundamental misconception by the district court of the principal issue in the case unavoidably skewed the remainder of its analysis.

Applying the principles set forth by the Supreme Court in *Chevron*, we examine whether Congress intended to give the FDA jurisdiction over tobacco products. Under *Chevron*, we first consider the intent of Congress because "[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842-43, 104 S. Ct. 2778. It is only if the intent of Congress is

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marketed with specific therapeutic claims such as weight loss. Unless indicated otherwise, all references in this opinion are to tobacco products as customarily marketed.

ambiguous that we defer to a permissible interpretation by the agency. *Chevron*, 467 U.S. at 843, 104 S. Ct. 2778. And we note, with emphasis, that the Supreme Court has stated that "[a] precondition to deference under *Chevron* is a congressional delegation of administrative authority." *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649, 110 S. Ct. 1384, 108 L.Ed.2d 585 (1990). Accordingly, no deference is due the FDA's construction of the Act unless it is acting within the bounds of its congressionally-established authority. If the court can ascertain Congress' intent on a particular question by applying the traditional rules of statutory construction, then it must give effect to that intent. *Chevron*, 467 U.S. at 843 n. 9, 104 S. Ct. 2778; see also *Cabell Huntington Hosp., Inc. v. Shalala*, 101 F.3d 984, 986 (4th Cir.1996) (stating that "[t]he goal of statutory interpretation is to implement congressional intent"). We also note that ascertaining congressional intent is of particular importance where, as here, an agency is attempting to expand the scope of its jurisdiction. See, e.g., *Adams Fruit Co.*, 494 U.S. at 650, 110 S. Ct. 1384 (quoting *Federal Maritime Comm'n v. Seatrain Lines, Inc.*, 411 U.S. 726, 745, 93 S. Ct. 1773, 36 L.Ed.2d 620 (1973)) (warning that "an agency may not bootstrap itself into an area in which it has no jurisdiction"); *ACLU v. FCC*, 823 F.2d 1554, 1567 n. 32 (D.C. Cir. 1987) (stating that "[w]hen an agency's assertion of power into new arenas is under attack, therefore, courts should perform a close and searching analysis of congressional intent, remaining skeptical of the proposition that Congress did not speak to such a fundamental issue"), *cert. denied*, 485 U.S. 959, 108 S. Ct. 1220, 99 L.Ed.2d 421 (1988); *Hi-Craft Clothing Co. v. NLRB*, 660 F.2d 910, 916 (3d Cir. 1981) (noting that "[t]he more intense scrutiny that is appropriate when

the agency interprets its own authority may be grounded in the unspoken premise that government agencies have a tendency to swell, not shrink, and are likely to have an expansive view of their mission").

Although the task of statutory construction generally begins with the actual language of the provision in question, *Mead Corp. v. Tilley*, 490 U.S. 714, 722, 109 S. Ct. 2156, 104 L.Ed.2d 796 (1989), the inquiry does not end there.[10] The Supreme Court has often emphasized the crucial role of context as a tool of statutory construction. For example, the Court has stated that when construing a statute, courts "must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." *United States Nat'l Bank of Oregon v. Independent Ins. Agents of America, Inc.*, 508 U.S. 439, 455, 113 S. Ct. 2173, 124 L.Ed.2d 402 (1993) (quoting *United States v. Boisdore's Heirs*, 49 U.S. (8 How.) 113, 122, 12 L.Ed. 1009, (1850)); see also *Regions Hosp. v. Shalala*, — U.S. ——, 118 S. Ct. 909, 139 L.Ed.2d 895 (1998); *Massachusetts v. Morash*, 490 U.S. 107, 115, 109 S. Ct. 1668, 104 L.Ed.2d 98 (1989). Thus, the traditional rules of statutory construction to be used in ascertaining congressional intent include: the overall statutory scheme, *Offshore Logistics, Inc. v. Tallentire*, 477 U.S.

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[10] In fact, if application of the plain language of a statute "would produce a result demonstrably at odds with the intent of Congress . . . the intent of Congress rather than the strict language controls." *Maryland State Dep't of Educ. v. U.S. Dep't of Veterans Affairs*, 98 F.3d 165, 169 (4th Cir. 1996) (citing *United States v. Ron Pair Enter., Inc.*, 489 U.S. 235, 242, 109 S. Ct. 1026, 103 L.Ed.2d 290 (1989)), *cert. denied*, — U.S. ——, 118 S. Ct. 43, 139 L.Ed.2d 10 (1997).

207, 220-221, 106 S. Ct. 2485, 91 L.Ed.2d 174 (1986) (directing courts to examine the language of the statute as a whole); legislative history, *Atherton v. FDIC*, 519 U.S. 213, 117 S. Ct. 666, 136 L.Ed.2d 656 (1997); "the history of evolving congressional regulation in the area," *Dunn v. CFTC*, 519 U.S. 465, 117 S. Ct. 913, 137 L.Ed.2d 93, (1997); and a consideration of other relevant statutes, *United States v. Stewart*, 311 U.S. 60, 64, 61 S. Ct. 102, 85 L.Ed. 40 (1940) (explaining that "all acts *in pari materia* are to be taken together as if they were one law") (italics in original). With these general principles in mind, we begin our inquiry into the issue of whether Congress intended to delegate jurisdiction over tobacco products to the FDA.

A. *Intrinsic Evidence*

The FDA correctly contends that the language of the statute must be the starting point of our analysis. We agree that the first step of statutory construction is determining the plain meaning of the statutory text. In fact, the Court instructs that the inquiry ends with the statutory language when the language is unambiguous and "the statutory scheme is coherent and consistent." *Robinson v. Shell Oil*, 519 U.S. 337, 117 S. Ct. 843, 136 L.Ed.2d 808 (1997) (quoting *Ron Pair Enter.*, 489 U.S. at 240, 109 S. Ct. 1026).

However, the flaw in the limited approach suggested by the FDA and taken by the district court is that they examine only the literal meaning of the statutory definitions of drug and device.[11] See FDA Red Br. at

[11] For example, in its jurisdictional analysis, the district court purported to examine the "Text of the Federal Food, Drug, and

34 (stating that "the jurisdictional inquiry is at an end with the conclusion that cigarettes and smokeless tobacco are 'intended to affect the structure of any function of the body' within the meaning of the Act's drug and device provisions"); see also *Coyne Beahm*, 966 F.Supp. at 1380.

A mechanical reading of only the definitions provisions may appear to support the government's position that tobacco products fit within the Act's definitions of drugs or devices. However, an initial problem with the government's theory is that the definitions of drug and device require not only that the article "affect the structure or any function of the body," but also that these effects be intended. 21 U.S.C. §§ 321(g)(1)(C), 321(h)(3). As noted by the district court, "no court has ever found that a product is 'intended for use' or 'intended to affect' within the meaning of the [Act] absent manufacturer claims as to that product's use." *Coyne Beahm*, 966 F. Supp. at 1390. Even the FDA does not contend that tobacco manufacturers make any such claims. *Coyne Beahm*, 966 F. Supp. at 1389 n. 14.

Even if we were to accept the FDA's position that no other inquiry is permissible if tobacco products fall within the literal definition of drug or device, the jurisdictional inquiry would not end there. Both the FDA and the district court failed to examine the literal definitions in view of the language and structure of the

Cosmetic Act." *Coyne Beahm*, 966 F.Supp. at 1380. However, the court mentioned only the definitions sections of the statute and ignored the text of all of the mandatory operative provisions of the Act.

Act as a whole. Such holistic approach to statutory construction is well-supported by the case law. See, e.g., *Robinson*, 519 U.S. 337, 117 S. Ct. 843, 136 L.Ed.2d 808 (stating that statutory language must be examined by "reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole"); *Gustafson v. Alloyd Co.*, 513 U.S. 561, 570, 115 S. Ct. 1061, 131 L.Ed.2d 1 (1995) (instructing that acts of Congress "should not be read as a series of unrelated and isolated provisions"); *United States Nat'l Bank*, 508 U.S. at 455, 113 S. Ct. 2173 (quoting *United Savings Ass'n of Texas v. Timbers of Inwood Forest Assoc., Ltd.*, 484 U.S. 365, 371, 108 S. Ct. 626, 98 L.Ed.2d 740 (1988)) (explaining that statutory interpretation is a "holistic endeavor" that must include, at a minimum, an examination of the statute's full text, its structure, and the subject matter). Accordingly, our task is to examine whether tobacco products fit into the overall regulatory scheme created by Congress.

According to FDA Deputy Commissioner Schultz, "[a] fundamental precept of drug and device regulation in this country is that these products must be proven safe and effective before they can be sold." Statement by FDA Deputy Commissioner William B. Schultz before the Senate Comm. on Labor and Human Resources, 104th Cong., p. 8 (Feb. 22, 1996). In fact, the FDA's congressionally-established mission statement provides that the FDA is charged with protecting the public health by ensuring that human drugs are "safe and effective" and that "there is a reasonable assurance of the safety and effectiveness of devices intended for human use." 21 U.S.C. § 393(b)(2)(B), (C). During its rulemaking, the FDA found that tobacco products are "dangerous," "unsafe," and the cause of "great pain and

suffering from illness such as cancer, respiratory illnesses, and heart disease." 61 Fed. Reg. at 44,412. In addition, the FDA determined that over 400,000 people die each year from tobacco use. 61 Fed. Reg. at 44,412. Yet, the FDA has proposed to regulate tobacco products under a statutory provision that requires conditions on sale and distribution which provide a reasonable assurance of safety. 21 U.S.C. § 360j(e). According to the FDA, a determination of safety under the Act requires consideration of the risks of a product compared to the "countervailing effects of use of that product, including the consequences of not permitting the product to be marketed." 61 Fed.Reg. at 44,412-13. Thus, the FDA concluded that withdrawal of tobacco from the market poses significant health risks to addicted adults which outweigh the risks of leaving tobacco products on the market. 61 Fed.Reg. at 44,405, 44,412-44,413.

But that test is contrary to the statute. The statutory provision, 21 U.S.C. § 360c(a)(2)(C), provides that safety and effectiveness are to be determined by "weighing any probable benefit to health from the *use* of the device against any probable risk of injury or illness from *such use*." See also *United States v. Rutherford*, 442 U.S. 544, 556, 99 S. Ct. 2470, 61 L.Ed.2d 68 (1979) (stating that "a drug is unsafe if its potential for inflicting death and physical injury is not offset by the possibility of therapeutic benefit"). According to the language of § 360c(a)(2)(C), the FDA's obligation is to strike a balance between the risks and benefits of the *use* of a certain product, not to weigh the risks of leaving a product on the market against the risks of taking a product off the market. The FDA is unable to state any real health benefit derived from leaving

tobacco products on the market. This is not to say that there are not other public policy reasons, such as impact on the national economy and the potential for a black market, weighing against a ban on tobacco products. However, this type of decision involving countervailing national policy concerns is just the type of decision left for Congress. By statute, the FDA's authority is limited to the balancing of health benefits and risks. 21 U.S.C. § 360c(a)(2)(C). Thus, its attempted analogy between tobacco products and chemotherapy drugs is not well taken. 61 Fed.Reg. at 44,413. These cancer-fighting drugs may be considered high-risk, but they have not been deemed "unsafe" by the FDA. Under the Act, the key to allowing these drugs to remain on the market is that their use produces affirmative health benefits which outweigh their risks. 21 U.S.C. § 360c(a)(2)(C). According to the FDA's own findings, tobacco products do not meet this test, for there is no health benefit from the use of tobacco. The FDA's inquiry into whether the risks of removing tobacco products from the market are greater than the risks of leaving them on the market is irrelevant under § 360c(a)(2)(C).

In the proposed regulations, the FDA characterized tobacco products as combination products containing drug and device components, but purported to regulate tobacco products as restricted devices under § 360j(e) of the Act. Section 360j(e) permits the FDA to place restrictions on the sale, distribution or use of a product which are necessary for a "reasonable assurance of safety" of the product. 21 U.S.C. § 360j(e). However, based on the FDA's characterization of tobacco products as unsafe, it is impossible to create regulations which will provide a reasonable assurance of safety.

Thus, the FDA cannot comply with the terms of the very statutory provision it has chosen as its basis for regulation. In addition to the fundamental conflicts described above, at least six internal inconsistencies arise when tobacco products are forced into the drug or device regulatory schemes of the Act.

First, § 355(a) of the Act requires that all new drugs be approved by the FDA before marketing. 21 U.S.C. § 355(a). The Act requires the FDA to disapprove applications for new drugs[12] if the drug is deemed unsafe or if there is not substantial evidence of its effectiveness. 21 U.S.C. § 355(d). This mandatory approval process presents an insurmountable problem for the FDA with respect to tobacco products because of the FDA's finding that they are unsafe. 61 Fed.Reg. at 44,412. In fact, the FDA has conceded that under the mandatory approval provisions, tobacco products would constitute unapproved new drugs. 60 Fed.Reg. 41,348 (1995) (FDA Proposed Rulemaking). As such, the Act would require the prohibition of the distribution and marketing of tobacco products. 21 U.S.C. §§ 331(d), 355(a).

The FDA attempts to avoid the problem inherent in the new drug approval requirement by classifying

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[12] In relevant part, the Act defines a "new drug" as:

> Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof
>
> . . .

21 U.S.C. § 321(p) (1).

tobacco products as combination products and then choosing to regulate them as devices rather than as drugs. The Act directs the FDA to determine the primary mode of action of a combination product. 21 U.S.C. § 353(g)(1). If the FDA determines that the primary mode of action is that of a drug, then it must assign "primary jurisdiction" over the product to the persons charged with premarket review of drugs. 21 U.S.C. § 353(g)(1)(A), (B). The FDA concedes that the "primary mode of action" of tobacco products is that of a drug.[13] FDA Red Br. at 26 (citing 61 Fed.Reg. at 45,209-18; 44,400-03). Yet, it chose to regulate tobacco products devices under § 360j(e) of the Act. This transparent action by the FDA, obvious sophistry, taken in order to avoid the new drug provisions of the Act, reinforces the conclusion that regulation of tobacco products under the Act was not intended by Congress. However, the FDA's classification of tobacco products as devices could not avoid similar problems caused by other provisions of the Act.

Section 331(a) of the Act prohibits the introduction into or delivery in interstate commerce of any drug o device that is misbranded. 21 U.S.C. § 331(a). Under § 352(j), a drug or device is deemed to be misbranded if it is dangerous to health when used in the manner suggested in the labeling. 21 U.S.C. § 352(j). The FDA has concluded that the use of tobacco products is

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[13] Interestingly, the FDA chose to regulate tobacco products as devices even though it has regulated the nicotine products within its jurisdiction—nicotine patches, nicotine gum, and nicotine nasal sprays—as drugs. Approved Drug Products with Therapeutic Equivalence Evaluations, 1762 Food Drug Cosm. L. Rep. (CCH) 3-220, 221 (FDA May 29, 1996).

dangerous to health. 61 Fed.Reg. at 44,412. Thus, it is impossible for the labeling of tobacco products to suggest a nondangerous use. Accordingly, §§ 331(a) and 352(j) operate to make the continued marketing of tobacco products illegal.

A drug or device is also considered misbranded, and thus prohibited under § 331(a), if it does not include "adequate directions for use." 21 U.S.C. § 352(f)(1). Accor ing to the FDA, the requirement of adequate directions for use means "directions under which the layman can use a device safely and for the purposes for which it is intended." 61 Fed.Reg. at 44,464. The FDA can exempt drugs and devices from § 352(f)(1)'s directions requirement, but only if the information is "not necessary for the protection of public health." 21 U.S.C. § 352(f). The FDA has previously interpreted § 352(f) to mean that an exemption from the direction requirements may be granted when other circumstances (such as a physician's prescription) can reasonably assure safe use of the drug or device. 21 C.F.R. §§ 201.100-201.129, 801.109-801.127 (1996).

The FDA now contends that an exemption for tobacco products is appropriate, 61 Fed.Reg. at 44,410, because everyone knows how to use tobacco products and thus directions are not needed. See 61 Fed.Reg. at 44,465 (stating that tobacco products are "one of the most readily available consumer products on the market today. Consequently, the way in which these products are used is common knowledge."). However, the FDA violated its own interpretation of the Act by exempting tobacco products under § 352(f) without any assurances of safety. Because of the FDA's finding that tobacco products are unsafe, 61 Fed.Reg. at 44,412, it is

impossible to provide directions for safe use as required by the statute. In addition, the exemption is inapplicable because no assurance of safety can be given for inherently unsafe products such as tobacco. Again, the FDA's need to apply the statutory exemption demonstrates that the Act does not and cannot apply to tobacco products.

Similarly, a drug or device is also considered misbranded, and thus prohibited by § 331(a), if it fails to bear "adequate warnings against use . . . by children where its use may be dangerous to health." 21 U.S.C. § 352(f)(2). Unlike § 352(f)(1), this section does not permit any exemptions from the warning requirement. In support of its proposed regulations, the FDA cited widespread use of tobacco products by minors and focused on controlling youth use as a means of decreasing tobacco-related illnesses and deaths. See 61 Fed. Reg. at 45,238-243 (characterizing youth use of tobacco products as a "pediatric disease"). The FDA concluded that the warnings mandated by other federal statutes satisfy the Act's requirement for adequate warnings to children even though none of the statutorily-prescribed warnings address the particular dangers of youth use repeatedly emphasized by the FDA. See 15 U.S.C. § 1333, 4402 (requiring Surgeon General warnings about health risks posed by tobacco products); see also 61 Fed. Reg. at 44,465. The FDA was constrained to find that the warnings mandated by other federal statutes are sufficient because the applicable federal statutes do not permit federal agencies to add to or modify the congressionally-mandated warnings. 15 U.S.C. §§ 1334(a), 4406(a). Again, the contortions that the FDA has gone through demonstrate

that Congress did not intend its jurisdictional grant to the FDA to extend to tobacco products.

Furthermore, under 21 U.S.C. § 360c(b)(1), all devices intended for human use must be classified into one of three categories, Class I, II, or III, based on ascending degrees of dangerousness. Placement is appropriate in the class that will provide a "reasonable assurance of the safety and effectiveness of the device." 21 U.S.C. § 360c(a)(1)(A)-(C). As discussed above, safety and effectiveness are determined by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C). Three years after it first introduced the proposed regulations, the FDA has yet to place tobacco products into one of the three categories. However, the agency's own findings with respect to dangers to health require classification of tobacco products as a Class III device subject to premarket approval because they "[present] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii)(II); see also 61 Fed. Reg. at 44,398, 44,412 (discussing dangers of tobacco use). Under the premarket approval process, tobacco products could not be approved without a showing that there is a reasonable assurance of safety and effectiveness of the products when used in the manner suggested by the labeling. 21 U.S.C. § 360c(a)(1)(C). The FDA contends that it will classify tobacco products at some point in the future and that the long delay is consistent with both the statutory framework and the agency's prior actions for other devices. 61 Fed.Reg. at 44,412; FDA Red Br. at 45. However, the real problem with attempting a classification is that all three categories of devices require reasonable assurances of safety and

effectiveness for the product. 21 U.S.C. § 360c(a)(1). As discussed earlier, the FDA cannot provide reasonable assurances of safety for a product that it has found to be inherently unsafe and dangerous. Thus, it has not, and more importantly, cannot comply with Congress' statutory classification directive because complying with the statute would trigger a ban on tobacco products, a result not intended by Congress.

Finally, the Act *requires* the FDA to issue an immediate cease-distribution order for all products found to cause "serious, adverse health consequences or death." 21 U.S.C. § 360h(e)(1).[14] This order begins an agency process that may ultimately result in a recall order for the device. 21 U.S.C. § 360h(e)(2). The FDA has found that "tobacco use is the single leading cause of preventable death in the United States. More than 400,000 people die each year from tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease, often suffering long and painful deaths." 61 Fed.Reg. at 44,398 (citations omitted). According to the terms of the Act, these findings, standing alone, mandate that the FDA issue a cease-distribution order

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[14] In relevant part, § 360h(e)(1) provides:

> If the [FDA] finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the [FDA] shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the device)
>
> (A) to immediately cease distribution of such device;
>
> . . .

21 U.S.C. § 360h(e)(1).

for tobacco products. Nevertheless, the FDA has no intention of complying with the requirements of the Act. See 61 Fed.Reg. at 44,419 (stating that the FDA will not ban tobacco products). The necessity of the FDA's avoidance of the statutory directives again demonstrates that Congress did not intend that the Act regulate tobacco products. A faithful application of the statutory language would lead to a ban on tobacco products—a result not intended by Congress.

The FDA makes a linguistic argument in an attempt to avoid the problem presented by this section. The statute provides that if the FDA finds there is a reasonable probability that a device will cause health problems or death, then the FDA "*shall* issue an order requiring . . . [the immediate] cease distribution of such device." 21 U.S.C. § 360h(e)(1)(A). However, the FDA contends that "shall" should be interpreted to mean "may." FDA Red Br. at 42-43. Even if we were to adopt this interpretation, the substance of our analysis would not change. As discussed above, the FDA has made the requisite finding of dangerousness under the statute. Thus, even if "shall" were interpreted as "may," the FDA still could exercise its discretion under the statute and ban tobacco products. And a failure to ban a product as dangerous as is tobacco, by the FDA's own findings, would necessarily be an abuse of discretion. But because an absolute ban falls outside the scope of congressional intent, construing the Act to cover tobacco products would be inconsistent with the will of Congress.

As demonstrated by the examples provided above, the FDA's need to maneuver around the obstacles created by the operative provisions of the Act reflects

congressional intent not to include tobacco products within the scope of the FDA's authority. The FDA argues that even if it has misapplied the Act, this error does not bear on the jurisdictional issue. However, the point is not merely that the FDA misapplied the Act, but these examples demonstrate the FDA's need to ignore and misapply the operative provisions of the Act before it can attain *its* end, not the end contemplated by Congress. Cf. *United States v. Two Plastic Drums*, 984 F.2d 814, 819 (7th Cir. 1993) (rejecting another recent attempt by the FDA to enlarge its jurisdiction and stating that "the only justification for this Alice-in-Wonderland approach is to allow the FDA to make an end-run around the statutory scheme"). The fact is that Congress did not equip the FDA with tools appropriate for the regulation of tobacco because it had no intention that the Act apply to tobacco products.

We do not dispute in this case that Congress has charged the FDA with protecting the public health and that tobacco products present serious health risks for the public. However, the Supreme Court has warned that "[i]n our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." *62 Cases of Jam v. United States*, 340 U.S. 593, 600, 71 S. Ct. 515, 95 L.Ed. 566 (1951). Based on our examination of the regulatory scheme created by Congress, we are of opinion that the FDA is attempting to stretch the Act beyond the scope intended by Congress.

B. *Extrinsic Evidence*

Pursuant to *Chevron*'s instruction to employ the traditional tools of statutory construction, we now examine the events surrounding the 1938 passage of the Act as well as subsequent statements and actions by Congress and the FDA. These individual events are like pieces of a puzzle in that no single event is outcome determinative. However, when viewed as a whole, it is clear that Congress did not intend to give the FDA jurisdiction over tobacco products in 1938 when it passed the Act. See *MCI Telecomm. Corp. v. AT & T*, 512 U.S. 218, 228, 114 S. Ct. 2223, 129 L.Ed.2d 182 (1994) (stating that relevant time for determining congressional intent on meaning of statute is when controlling statute enacted). As discussed above, the fact that the operative provisions of the Act simply cannot accommodate tobacco products is a clear indication of congressional intent. Cf. *Gustafson*, 513 U.S. at 569, 115 S. Ct. 1061 (explaining that an operative provision of the Securities Act of 1933 does not define prospectus, the term at issue, but "does instruct us what a prospectus cannot be if the Act is to be interpreted as a symmetrical and coherent regulatory scheme"). Subsequent events outside the language of the statute only confirm our understanding of Congress' intent.

1. *Historical Actions of the FDA*

From 1914 until the present rulemaking attempt, the FDA had consistently stated that tobacco products were outside the scope of its jurisdiction. And, as early as 1898, the Supreme Court of Tennessee acknowledged the dangerous nature of tobacco products, characteriz-

ing cigarettes as "wholly noxious and deleterious to health," "inherently bad, and bad only," and "widely condemned as pernicious altogether." *Austin v. State*, 101 Tenn. 563, 48 S.W. 305, 306 (1898). Yet, the statute preceding the Act, the Pure Food and Drugs Act of 1906, Pub.L. No. 59-384, 34 Stat. 768 (1906), did not mention tobacco. As early as 1914, the FDA's predecessor agency stated that it had authority to regulate tobacco products if their labeling indicated use for "the cure, mitigation, or prevention of a disease," but not if labeled or used for "smoking or chewing or as snuff and not for medicinal purposes." Bureau of Chemistry, U.S. Dept. of Agriculture, 13 *Service and Regulatory Announcements* 24 (Apr. 2, 1914). Enacted in 1938, the present Act expanded the definition of drug from the definition provided in the Pure Food and Drugs Act of 1906 and also granted the FDA new authority to regulate "devices." Food, Drug, and Cosmetic Act, Pub.L. No. 75-717, 52 Stat. 1040 (1938). However, neither the Act nor its legislative history mention tobacco products.[15]

In the 60 years following the passage of the Act, the FDA has repeatedly informed Congress that cigarettes marketed without therapeutic claims do not fit within the scope of the Act. Ever since its beginning in the 1930s, the FDA has taken the position and made

[15] Two of the main supporters of the Act were representatives from the two leading tobacco States—Senator Bailey (D-NC) and Representative Chapman (D-KY). See 83 Cong. Rec. 9094 (1938). In fact, Sen. Bailey and Rep. Chapman were among Senate and House managers of the Act in the Conference Committee. Had there been any indication that the Act might apply to tobacco products, we can only assume that such members of Congress would have expressed opposition to the Act.

statements indicating that the Act did not apply to cigarettes marketed without specific health claims. FDA/Dep't of Justice Brief in *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980), at 16. Again, in 1963, an FDA Bureau of Enforcement Guideline stated that "[t]he statutory basis for the exclusion of tobacco products from FDA's jurisdiction is the fact that tobacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions in the Food, Drug, and Cosmetic Act for food, drug, device or cosmetic." Letter to Directors of Bureaus and Divisions and Directors of Districts from FDA Bureau of Enforcement (May 24, 1963), *reprinted in* Public Health Cigarette Amendments of 1971: Hearings Before the Consumer Subcomm. of the Senate Comm. on Commerce on S. 1454, 92d Cong. 240 (1972). When Congress later examined the issue of the FDA's jurisdiction during its consideration of tobacco-specific legislation, FDA Commissioner Charles Edwards testified regarding the FDA's lack of authority over cigarettes and stated that "if cigarettes were to be classified as drugs, they would have to be removed from the market because it would be impossible to prove they were safe for their intended [use]."[16] Hearings on S. 1454 at 239. The Commissioner took the position that the Federal Cigarette Labeling and Advertising Act, discussed in greater detail below, reinforced that "the

[16] The Commissioner cited several cases in support of the FDA's conclusion that it lacked authority over cigarettes as customarily marketed. See, e.g., *FTC v. Liggett & Myers Tobacco Co.*, 203 F.2d 955 (2d Cir. 1953), *affirming on opinion below*, 108 F. Supp. 573 (S.D.N.Y.1952); *United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F.Supp. 847 (D.N.J. 1959); *United States v. 46 Cartons . . . Fairfax Cigarettes*, 113 F. Supp. 336 (D.N.J. 1953).

regulation of cigarettes is to be the domain of Congress." Hearings on S. 1454 at 242. The Commissioner then concluded that "labeling or banning cigarettes is a step that can be take[n] only by Congress. Any such move by the FDA would be inconsistent with the clear congressional intent." Hearings on S. 1454 at 242.

In 1977, Action on Smoking and Health (ASH), a public health group, petitioned the FDA to regulate cigarettes. ASH claimed that cigarettes were drugs because they contain nicotine which produces addiction in many smokers, and particularly in youth. Citizen Petition, FDA Docket No. 77P-0185, at 4-11 (May 26, 1977)[G. Br. Att. 77]. In rejecting ASH's petition,[17] the FDA cited a 1953 Second Circuit opinion, *FTC v. Liggett & Myers Tobacco Co.*, 203 F.2d 955 (2d Cir. 1953), *affirming on opinion below*, 108 F. Supp. 573 (S.D.N.Y. 1952), for the proposition that cigarettes marketed without health claims by the vendor are not within the FDA's jurisdiction. Specifically, the FDA quoted with approval the following language from the court's opinion:

> The legislative history, such as it is, coupled with indications of contemporaneous administrative interpretation leads me to the conclusion that Congress, had the matter been considered, would not have intended cigarettes to be included as an article "intended to affect the functions of the body of man" or in any other definition of "drug."

[17] A federal appeals court upheld the FDA's denial of jurisdiction. See *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980). In upholding the FDA's denial of jurisdiction, the court emphasized the relevance of the remarks of the district court in *Liggett*. In construing the identical language of the definitions in the Federal Trade Commission Act, the *Liggett* court stated: "[s]urely, the legislators did not mean to be as all-inclusive as a literal interpretation of [the definitions] would compel us to be." *ASH*, 655 F.2d at 240 (quoting *Liggett & Myers*, 108 F. Supp. at 576).

See Letter from FDA Commissioner Donald Kennedy to John F. Banzhaf, III, at 3 (Dec. 5, 1977) (quoting *Liggett & Myers*, 108 F. Supp. at 577) (stating that the FDA's consistent position has been that cigarettes marketed without health claims by vendors are not drugs within the Act).

In 1978, ASH filed a second petition, claiming that cigarettes were devices under the Act and thus were within the scope of the FDA's jurisdiction. *Citizen Petition*, FDA Docket No. 78P-0338 (Oct. 2, 1978). After reviewing the legislative history of the Act, the FDA stated that "[i]nsofar as rulemaking would relate to cigarettes or attached filters as customarily marketed, we have concluded that FDA has no jurisdiction under [the definition of device]. Therefore, no rulemaking is permissible *as a matter of law*." Letter from FDA Commissioner Jere E. Goyan to John F. Banzhaf, III and Peter N. Georgiades, at 12 (Nov. 25, 1980). In considering the effect of the Medical Device Amendments of 1976 which modified the definition of device to its current formulation, the FDA Commissioner stated:

> Specifically, there is no evidence in the legislative history that Congress intended to include cigarettes within the definition of "device" nor does the legislative history contain any discussion of a possibility that cigarettes were "devices" within the prior definition.

> The amendments were thoroughly considered, and the legislative history discusses the types of products intended to be regulated and the types of health hazards with respect to which the amendments were intended to provide authority. Cigarettes are not mentioned even though Congress was aware of the considerable public discussion of the health hazards of cigarette smoking. It is, therefore, not reasonable to consider cigarettes as "devices" when there was no discussion in the legislative history of congressional intent to provide jurisdiction over cigarettes or to provide authority suitable to the regulation of cigarettes.

Goyan/Banzhaf Letter, at 3. The FDA's holdings and statements that the Act fails to provide "authority suitable to the regulation of cigarettes" are consistent with part II.A's conclusion, *supra*, that the Act's regulatory scheme simply cannot accommodate tobacco products.

Again in 1989, the FDA Commissioner stated that: "it doesn't look like it is possible to regulate [tobacco products] under the Food, Drug and Cosmetic Act even though smoking, I think, has been widely recognized as being harmful to human health." Hearings Before the Subcomm. on Rural Development, Agriculture, and Related Agencies of the House Comm. on Appropriations, 100th Cong., 2d Sess. 409 (1989). The above statements evidence the FDA's position from 1914 until the present rulemaking attempt that, as a matter of law, it did not have jurisdiction to regulate tobacco products as customarily marketed. The FDA's public,

consistent, and longstanding interpretation[18] of the Act gains even more significance when viewed in conjunction with the actions of Congress during the same time period.

2. *Congressional Inaction*

We recognize the general reluctance of courts to rely on congressional inaction as a basis for statutory interpretation. See *Brecht v. Abrahamson*, 507 U.S. 619, 632, 113 S. Ct. 1710, 123 L.Ed.2d 353 (1993) (noting that "[a]s a general matter, 'we are reluctant to draw inferences from Congress's failure to act'") (quoting *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 306, 108 S. Ct. 1145, 99 L.Ed.2d 316 (1988)). However, under certain circumstances, inaction by Congress may be interpreted as legislative ratification of or acquiescence to an agency's position. See *Bob Jones Univ. v. United States*, 461 U.S. 574, 601, 103 S. Ct. 2017, 76 L.Ed.2d 157 (1983) (stating that "[i]n view of its prolonged and acute awareness of so important an issue, Congress' failure to act on the bills proposed on this subject provides added support for concluding that Congress acquiesced in the IRS rulings"). In *Bob Jones*, the Court examined Congress' failure to modify

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[18] We do not mean to suggest that an agency is always irrevocably bound by its prior interpretations of a statute. However, we note that an agency's interpretation of a statutory provision that conflicts with the agency's earlier interpretation is "entitled to considerably less deference' than a consistently held agency view." *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417, 113 S. Ct. 2151, 124 L.Ed.2d 368 (1993) (quoting *Watt v. Alaska*, 451 U.S. 259, 273, 101 S. Ct. 1673, 68 L.Ed.2d 80 (1981)). In addition, the evidence of legislative ratification also weighs against the FDA's actions in the present case.

two IRS rulings when the public and Congress were well aware of the position of the IRS. *Bob Jones*, 461 U.S. at 599-602, 103 S. Ct. 2017. In finding legislative acquiescence to the IRS position, the Court emphasized: extensive hearings held by Congress on the issue; the introduction and failure of numerous bills in Congress introduced to overturn the IRS's interpretation of the Internal Revenue Code; and Congress' awareness of the IRS position when enacting other, related legislation. *Bob Jones*, 461 U.S. at 599-601, 103 S. Ct. 2017; see also *United States v. Riverside Bayview Homes, Inc.*, 474 U.S. 121, 137, 106 S. Ct. 455, 88 L.Ed.2d 419 (1985) (finding legislative acquiescence and explaining that "a refusal by Congress to overrule an agency's construction of legislation" is particularly relevant "where the administrative construction has been brought to Congress' attention through legislation specifically designed to supplant it").

We are of opinion that the matter before us presents an equally strong case of legislative acquiescence.[19] As noted by the district court, Congress has introduced numerous bills that would have granted the FDA jurisdiction over tobacco products. See *Coyne Beahm*, 966 F. Supp. at 1382 (stating that "members of Congress agreed with FDA's assertions that it lacked jurisdiction" and thus introduced bills expressly granting the FDA jurisdiction "in an effort to remedy the situation"). In fact, the district court listed 15

[19] The district court attempted to distinguish the *Bob Jones* and *Riverside Bayview* cases by noting that they involved agency action rather than statements by an agency that it did not have jurisdiction to act. *Coyne Beahm*, 966 F. Supp. at 1383. We fail to see any real distinction and thus find the cases applicable.

different bills introduced in Congress which would have expressly granted the FDA jurisdiction over tobacco products. *Coyne Beahm*, 966 F. Supp. at 1382. However, none of these bills were enacted. As discussed above, FDA officials have testified at many congressional hearings regarding the FDA's lack of jurisdiction over tobacco products. See also *Coyne Beahm*, 966 F.Supp. at 1381. Thus, Congress has been well aware of the FDA's position that it lacked jurisdiction over tobacco products since 1914. On several occasions, Congress has enacted legislation to deal specifically with the dangers of tobacco products, but has never enacted legislation to overturn the FDA's interpretation of its jurisdiction under the Act. Accordingly, this is not a case where congressional inaction demonstrates "unawareness, preoccupation, or paralysis." See *Zuber v. Allen*, 396 U.S. 168, 185-86 n. 21, 90 S. Ct. 314, 24 L.Ed.2d 345 (1969). We believe that the actions rejected and taken by Congress with respect to the regulation of tobacco provide strong evidence of congressional intent that it, and not the FDA, controls the regulation of tobacco products.

3. *Congress' Tobacco-Specific Legislation*

Under *Chevron*'s instruction to apply the traditional rules of statutory construction, it is also appropriate to consider the provisions of the "whole law, and . . . its object and policy" in ascertaining the will of Congress. *Dole v. United Steelworkers of America*, 494 U.S. 26, 35, 110 S. Ct. 929, 108 L.Ed.2d 23 (1990) (quoting *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 51, 107 S. Ct. 1549, 95 L.Ed.2d 39 (1987)). Having examined the Act and prior actions of the FDA and Congress, we now take a closer look at three statutes and related amend-

ments (collectively referred to as the tobacco-specific legislation) enacted by Congress for the purpose of addressing public health concerns about the use of tobacco products.

The issue is not, in the words of the stalking horse set up by the government, whether these three statutes partially repeal or amend the Act to withhold jurisdiction over tobacco products from the FDA. FDA Red Br. at 57. Rather, we examine the tobacco-specific legislation as a part of our inquiry into congressional intent. As discussed above, we are of opinion that the statutory text, viewed as a coherent whole, clearly indicates that Congress did not intend the FDA's original jurisdictional grant to include tobacco products. Thus, the subsequent enactment of tobacco-specific legislation provides corroborating evidence of established congressional intent.

In January 1964, the publication of the first Surgeon General's report on smoking and health called the federal government's attention to the dangers of tobacco products. Dept. of Health, Education and Welfare, *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service* (1964); see also H.R. Rep. No. 289, 91st Cong., 1st Sess., at 5 (characterizing the 1964 Surgeon General's Report as the "principal basis" for regulatory efforts). Shortly thereafter, the House Committee on Interstate and Foreign Commerce initiated a series of hearings regarding the federal government's role in dealing with smoking-related health problems. Committee Chairman, Representative Oren Harris, stated that:

> The purpose of these hearings will be, if we can reach that point, to determine the extent of authority under existing law to deal with the various aspects of this general field, and to determine whether any action of the Congress is warranted in the interest of public health. In other words, we want to find out under our responsibility whether or not legislative action is necessary, and if so, what kind.

Hearings Before the Comm. on Interstate and Foreign Commerce on Bills Regulating the Labeling and Advertising of Cigarettes and Relating to Health Problems Associated with Smoking, 88th Cong., 2d Sess. 23 (1964).

During the course of these hearings, Congress considered and rejected the option of granting the FDA jurisdiction over tobacco products. Of the eleven bills submitted to the Committee, two would have expressly amended the Act to make it applicable to tobacco products. 1964 Hearings at 2-12. These two bills proposed expansion of the Act to cover tobacco products by creating a new category of products subject to FDA jurisdiction. See 1964 Hearings at 4-7 (suggesting creation of new category entitled "smoking products"). These two bills also proposed new operative provisions applicable only to "smoking products."[20] 1964 Hearings at 4-7. As part of the hearings, Surgeon General Terry was asked whether the Department of Health, Education, and Welfare (HEW), the FDA's parent depart-

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[20] The fact that the two proposed bills created a new jurisdictional category and new operative provisions for tobacco products is consistent with our analysis in part II.A, *supra*, which concludes that the current structure of the Act cannot accommodate tobacco products.

ment, had authority to regulate tobacco products. Dr. Terry's unqualified response was that his department did not believe that it had "such authority in existing laws governing the Public Health Service and Food and Drug Administration." 1964 Hearings at 56. Similar testimony was later provided by the Deputy Commissioner of the FDA. See Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce, 89th Cong., 2d Sess. 193 (1965) (statement of Deputy Commissioner Rankin that "[t]he Food and Drug Administration has no jurisdiction under the Food, Drug, and Cosmetic Act over tobacco, unless it bears drug claims"); see also 111 Cong. Rec. 13431 (1965). In addition, the Secretary of HEW, Anthony J. Celebrezze, warned the Committee that giving the FDA jurisdiction over tobacco products "might well" lead to a ban and that such a ban would be contrary to the intent of Congress and the will of the American public. See 1964 Hearings at 18 (stating that a ban would be "contrary to what, we understand, is intended or what, in the light of our experience with the 18th amendment, would be acceptable to the American people").

Following the hearings and consideration of the various bills, Congress responded to the Surgeon General's report by enacting The Federal Cigarette Labeling and Advertising Act (Cigarette Labeling Act), Pub.L. No. 89-92, 79 Stat. 282 (1965) (codified at 15 U.S.C. §§ 1331 *et seq.*). In general, the Cigarette Labeling Act required manufacturers to place specific health-hazard warnings from the Surgeon General on cigarette packaging, advertising, and billboards. 15 U.S.C. § 1333. The Cigarette Labeling Act also set forth con-

gressional policy regarding regulation of tobacco products:

> It is the policy of the Congress, and the purpose of this chapter, to establish a *comprehensive Federal program* to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby
>
> (1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and
>
> (2) *commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.*

15 U.S.C. § 1331. Thus, the express goal of the Cigarette Labeling Act is to warn consumers about the health hazards of smoking while also protecting the national economy.

The district court apparently considered that the plaintiffs claimed that the separate preemption provision of the Cigarette Labeling Act precluded any further regulation of tobacco products except by Congress. See *Coyne Beahm*, 966 F. Supp. at 1385-1386. We do not think that the claim was so broad then, certainly it is not so broad now. While it is true that 15 U.S.C. § 1334, requires that no statement relating to smoking or health other than the statement required by § 1333, shall be required on any cigarette package, that

is not a statement excluding other regulation of tobacco products. But the fact that Congress has, some 27 years after the establishment of the FDA in its present form, enacted the Cigarette Labeling Act, is strong evidence that Congress has reserved for itself the regulation of tobacco products rather than delegating that regulation to the FDA.

Congressional policy, as set out in the Cigarette Labeling Act, cannot be harmonized with the FDA's assertion of jurisdiction over tobacco products. First, by enacting the Cigarette Labeling Act rather than other proposed legislation, Congress clearly rejected the proposed regulatory role for the FDA. Next, the Act charges the FDA with protecting the public health, but does not authorize the FDA to consider protection of commerce and the national economy. Thus, by the terms of its enabling statute, the FDA is not capable of complying with Congress' stated policy regarding the regulation of tobacco products. In addition, the congressionally-established regulatory plan of the Cigarette Labeling Act directly contradicts the FDA's mandatory requirements set forth in the Act. As discussed *supra* in part II.A, the Act prohibits the sale or distribution of unsafe devices. See, e.g., 21 U.S.C. §§ 331(a), 352(j). In contrast, the Cigarette Labeling Act recognizes the unsafe and dangerous nature of cigarettes, but permits continued marketing with consumer warnings. 15 U.S.C. §§ 1331, 1333. The decision by Congress to allow continued marketing of unsafe products cannot be reconciled with the operative provisions of the Act, primarily because the Act does not allow FDA consideration of the factors involved in Congress' policy determination. See 15 U.S.C. § 1331(2)

(establishing policy of protecting "commerce and the national economy").

Finally, in developing the Cigarette Labeling Act, Congress clearly considered and rejected a role for the FDA. The government does not produce any legislative history to the contrary. The legislative history of the Cigarette Labeling Act is thus important to understanding congressional intent because it reflects the historical context in which the Cigarette Labeling Act was developed. See *Radowich v. United States Att'y*, 658 F. 2d 957, 961 (4th Cir. 1981) (stating that courts should look at the "clearly expressed intention as expressed without dissent in the legislative history" to be certain that their construction of a statute is consistent with the "manifest purpose as clearly mirrored in the legislative history"). Thus, the Cigarette Labeling Act and the context in which it was enacted provides evidence of Congress' intent that the FDA not have jurisdiction over tobacco products. Subsequent legislation by Congress reinforces our understanding of this expressed congressional intent.

The Cigarette Labeling Act's advertising and labeling regulations originally were set to expire on June 30, 1969. In response, the Federal Communications Commission (FCC) introduced a proposal to ban all television and radio cigarette advertising. 34 Fed.Reg. 1959 (1969). In addition, the Federal Trade Commission (FTC) renewed its proposed rule from 1964. See 34 Fed. Reg. 7917 (1969) (citing health hazards of smoking and proposing warning statements for cigarette packages and advertisements).[21] Again, Congress debated

[21] We note that the FDA took no action at this time.

the role of administrative agencies in the regulation of tobacco products. See generally Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce, 91st Cong., 1st Sess. (1969). The House Report stated:

> The regulations [proposed by the FCC and the FTC] raise basic constitutional questions and would affect the growing, sale, and manufacturing of tobacco for cigarettes and the persons involved in or affected by those activities. These activities cut across the whole spectrum of commercial and social life in the United States. It is therefore an area where the Congress, if anyone, must make policy.
>
> . . .
>
> Aside from the questions of constitutional and statutory law which the two agencies' proposed rules raise, they are an assumption by these agencies of policymaking with respect to a subject matter on which the Congress has made policy . . ., [and] has stated its intention to be the exclusive policymaker on the subject matter. . . .

H.R.Rep. No. 289, at 4-5.

Following these debates and hearings, Congress amended the Cigarette Labeling Act by enacting the Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91- 222, 84 Stat. 87 (1970). Basically, the 1969 Act reenacted the Cigarette Labeling Act, but with several amendments.[22] Notably, Congress did not amend or

[22] For example, the 1970 amendments changed the wording of the warning to be included on cigarette packages, 15 U.S.C. § 1333;

replace 15 U.S.C. § 1331, the provision setting out its policy determination regarding the regulation of tobacco products.

Congress showed a continuing interest in the regulation of tobacco products with the Alcohol and Drug Abuse Amendments of 1983, Pub. L. No. 98-24, 97 Stat. 175, 178 (1983) (codified at 42 U.S.C. §§ 290aa *et seq.*). These amendments require the Secretary of HHS, FDA's parent agency, to submit certain reports to Congress every three years. 42 U.S.C. § 290aa-2(b). The statute directs the Secretary to report to Congress current findings on "the addictive property of tobacco" and to *recommend* "legislation and administrative action as the Secretary may deem appropriate." 42 U.S.C. § 290aa-2(b)(2)-(3). This statute evidences Congress' awareness of the addictive nature of tobacco products and its intent to retain control over further regulatory action.

In 1984, Congress again amended the Cigarette Labeling Act, but retained the basic regulatory approach established in 1965. See Comprehensive Smoking Education Act (Smoking Education Act), Pub. L. No. 98-474, 98 Stat. 2200 (1984) (amending the Cigarette Labeling Act). The Smoking Education Act required rotating warnings on cigarette packaging and advertising, 15 U.S.C. § 1333; established an Interagency Committee on Smoking and Health, including members from the FTC, the Department of Education, and the Department of Labor, but not from the FDA,

revised § 1334's express preemption provision; and made it unlawful to advertise cigarettes on electronic communications subject to FCC jurisdiction, 15 U.S.C. § 1335.

15 U.S.C. § 1341(b); and required annual disclosure of tobacco ingredients to the Secretary of HHS, 15 U.S.C. § 1335a. Quoting U.S. Surgeon General Dr. C. Everett Koop, the House Report recommending this legislation described cigarette smoking as "the most important public issue of our time." H.R.Rep. No. 805, 98th Cong., 2d Sess., at 12 (1984). Consistent with the prior actions of Congress discussed above, the House Report recognized that "[f]ederal laws that protect the public from hazardous food, drugs and consumer products do not apply to cigarettes." H.R. Rep. 805, at 12.

In 1986, Congress created a similar regulatory program for smokeless tobacco, but with some additions.[23] Comprehensive Smokeless Tobacco Health Education Act (Smokeless Tobacco Act), Pub.L. No. 99-252, 100 Stat. 30 (1986) (codified at 15 U.S.C. §§ 4401-4408). In general, the Smokeless Tobacco Act required specific health warnings in smokeless tobacco advertising and on packaging, 15 U.S.C. § 4402(a),(b); authorized the FTC to issue specified regulations regarding the content and form of label warnings, 15 U.S.C. § 4402(c); banned advertising on electronic communications subject to FCC jurisdiction, 15 U.S.C. § 4402(f); and required annual ingredient and nicotine-level reporting to the HHS Secretary, 15 U.S.C. § 4403. In addition, the Smokeless Tobacco Act authorized the Secretary of HHS to develop a program for informing the public of the health hazards caused by use of smokeless tobacco. 15 U.S.C. § 4401(a). Specifically, the Secretary is

[23] It is worth noting that Congress adopted a very similar approach to the one taken in the Cigarette Labeling Act, even though it had expressly recognized the addictive nature of tobacco. 42 U.S.C. § 290aa-2(b)(2).

instructed to make this information available to school systems for educational purposes. 15 U.S.C. § 4401(a)(1)(B). The statute also provided for technical and financial assistance to States for their development of educational programs about the dangers of smokeless tobacco and for establishing 18 as the minimum age for purchasing smokeless tobacco. 15 U.S.C. § 4401(b).[24] Finally, the Smokeless Tobacco Act requires the Secretary of HHS to submit biennial reports to Congress containing "a description of the effects of health education efforts," "an evaluation of the health effects of smokeless tobacco products," and "recommendations for legislation and administrative action." 15 U.S.C. § 4407(a).

Like the Cigarette Labeling Act, the Smokeless Tobacco Act also contains an express preemption provision. See 15 U.S.C. § 4406 (providing that "[n]o statement relating to the use of smokeless tobacco products and health, other than the statements required by section 4402 of this title, shall be required by any Federal agency to appear on any package or in any advertisement"). However, as discussed in relation to the Cigarette Labeling Act, this express preemption provision does not detract from our examination of the statute as a tool for determining congressional intent. In recommending passage of the Smokeless Tobacco Act, the House Report cited particular concerns about the popularity of smokeless tobacco with minors. See S. Rep. No. 209, 99th Cong., at 4 (1985), *reprinted in* 1986

[24] As discussed below, Congress built on the youth education and age limit provisions of the Smokeless Tobacco Act in the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 (1992 Amendments), Pub.L. No. 102-321, 106 Stat. 394 (codified at 42 U.S.C. § 300x-26).

U.S.C.C.A.N. 7, 10 (stating that "a major reason for the development of a legislative proposal is the alarming incidence of use by children"). Thus, in 1986, Congress considered the very issues that the FDA now purports to address in its proposed regulations.

Within the context of the FDA's repeated stated positions that it had no jurisdiction, Congress enacted comprehensive legislation addressing many of the activities that the FDA now attempts to regulate, based on the same concerns relating to youth use now cited by the FDA. The enactment of the Smokeless Tobacco Act in no way supports a conclusion that Congress intended to give the FDA jurisdiction over tobacco products. To the contrary, the detailed scheme created by Congress evidences its intent to retain authority over regulation of smokeless tobacco. Cf. *Patterson v. McLean Credit Union*, 491 U.S. 164, 181, 109 S. Ct. 2363, 105 L.Ed.2d 132 (1989) (stating that courts "should be reluctant . . . to read an earlier statute broadly where the result is to circumvent the detailed remedial scheme constructed in a later statute"). The FDA may not, without empowerment by Congress, construct what it believes is a "better" regulatory scheme. *MCI*, 512 U.S. at 234, 114 S. Ct. 2223. If the FDA believed that additional regulation was needed, the Secretary should have recommended such action to Congress, as directed in the Smokeless Tobacco Act. 15 U.S.C. § 4407(a)(4).

In 1992, Congress again addressed the problem of youth access to tobacco products. The Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 (1992 Amendments), Pub. L. No. 102-321, 106 Stat. 394, focused on regulation at the state level by providing financial incentives to States which

enact and enforce access restrictions for individuals under age 18. 42 U.S.C. § 300x-26.[25]

The 1992 Amendments express clear congressional intent that States exercise their traditional police powers and take a primary role in attacking the problem of youth access to tobacco products. However, the FDA's proposed regulatory scheme would preempt much state regulation in this area, including more stringent regulations than those proposed by the FDA. The Act prohibits States from imposing on devices any requirements "different from, or in addition to" those imposed by the FDA. 21 U.S.C. § 360k(a). Thus, if the Act applied to tobacco products, § 360k(a) would prohibit States from addressing the problem of youth access. The FDA responds, FDA Red Br. p. 67, n. 16, that States "might" qualify for exemptions from preemption under § 360k(b). However, the possibility of a discretionary exemption does not take away the inherent conflict between the state regulatory role established by Congress and the FDA's proposed scheme. In developing its regulatory scheme for tobacco products, Congress made a policy determination that state participation was necessary for effective regulation of

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[25] More specifically, States are eligible for the financial incentives only if they: (1) prohibit sales to individuals under age 18, 42 U.S.C. § 300x26(a)(1); (2) enforce the prohibition in a way that "can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18," 42 U.S.C. § 300x- 26(b)(1); (3) conduct "random, unannounced inspections" of retailers to check compliance, 42 U.S.C. § 300x-26(b)(2)(A); and (4) make annual reports to the HHS Secretary regarding the manner and success of state enforcement activities, 42 U.S.C. § 300x-26(b)(2)(B).

youth access. Allowing the FDA to override this decision would be contrary to congressional intent.

Over the last 60 years, Congress has enacted numerous statutes and amendments for the regulation of tobacco products. Throughout this period, Congress was well aware of the dangers of tobacco products and of the FDA's consistent position that it had no jurisdiction over tobacco products. Yet, Congress took no steps to overturn the FDA's interpretation of the Act, that it had no jurisdiction over tobacco products as customarily used. In fact, Congress deliberately rejected a role for the FDA during its consideration of various legislation from 1965 through 1993.[26] Instead, Congress developed a regulatory scheme whereby it retained the position of policymaker for the industry.[27] In addition, it developed a scheme whereby designated agencies would periodically report any new information and recommendations for legislation or regulation to Congress.[28] Taken together, these actions by Congress are relevant and corroborative evidence that Congress never intended to give the FDA jurisdiction over tobacco products.

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[26] Between 1965 and 1993, at least 13 bills were introduced in Congress which would have given the FDA jurisdiction over tobacco products. None of these bills were enacted.

[27] Although Congress has given the FTC limited authority to regulate advertising related to tobacco products, this power is limited by the tobacco-specific legislation. 15 U.S.C. §§ 1336m, 4404-06.

[28] The HHS, FTC, and Interagency Committee are all directed to make periodic reports to Congress including information on the health effects of tobacco products, the addictive nature of tobacco products, cigarette advertising. See e.g., 15 U.S.C. §§ 1337(a), (b), 1341(a)-(c); 42 U.S.C. § 290aa-2.

III. *Conclusion*

This is not a case about whether additional or different regulations are needed to address legitimate concerns about the serious health problems related to tobacco use, and particularly youth tobacco use, in this country. At its core, this case is about who has the power to make this type of major policy decision. As the Supreme Court has previously stated about a different agency and its enabling statute, neither federal agencies nor the courts can substitute their policy judgments for those of Congress. See *MCI*, 512 U.S. at 234, 114 S. Ct. 2223 (stating that "our estimations, and the [FCC's] estimations, of desirable policy cannot alter the meaning of the federal Communications Act of 1934"). In rejecting the agency's interpretation of its enabling statute, the *MCI* Court characterized the agency's action as "effectively the introduction of a whole new regime of regulation . . . which may well be a better regime but is not the one that Congress established." *MCI*, 512 U.S. at 234, 114 S. Ct. 2223. Accordingly, we do not, indeed cannot, pass judgment on the merits of the regulatory scheme proposed by the FDA. By its *ultra vires* action, the FDA has exceeded the authority granted to it by Congress, and its rulemaking action cannot stand.

We are thus of opinion that Congress did not intend to delegate jurisdiction over tobacco products to the FDA. Accordingly, the judgment of the district court is

REVERSED.[29]

[29] This footnote is added to make clear that the judgment of the district court regarding the construction of 21 U.S.C. § 360j(e), *Coyne Beahm*, 966 F. Supp. at 1399-1400, is vacated. The district court's construction of § 360j(e) was based on its erroneous holding that the FDA had authority to promulgate regulations regarding tobacco products. Had the district court reached the correct conclusion on the jurisdictional issue, there would have been no occasion to address the construction of § 360j(e). Accordingly, we vacate the district court's decision on that issue which is the subject of the government's appeal. We express no opinion on that question, and our decision should not be construed as either agreeing with or disagreeing with the district court's decision on the construction of § 360j(e).

K.K. HALL, Circuit Judge, dissenting:

The FDCA delegates to the FDA the duty of promulgating and enforcing regulations aimed at protecting the nation's citizens from misbranded and unsafe drugs and food. After years of considering an array of evidence, much of it only recently brought to light, the FDA decided to regulate a product that is estimated to cause some 400,000 deaths a year. While not actually disputing that tobacco products deliver a drug, nicotine, into the body, the majority would deny to the FDA the authority to act to address this acknowledged health threat. I dissent.

Tobacco products fit comfortably into the FDCA's definitions of "drug" and "device." Inasmuch as cigarettes and smokeless tobacco are responsible for illness and death on a vast scale, FDA regulations aimed at curbing tobacco use by children cannot possibly be contrary to the general intent of the FDCA to protect the public health. But even when we expand our search for legislative intent beyond the words of the statute, the evidence falls far short of demonstrating that Congress intended to deny or withdraw jurisdiction over tobacco from the FDA. Therefore, on the major question before us, I would affirm the district court's denial of summary judgment to the companies to the extent such judgment turns on the issue of the FDA's authority to regulate tobacco products.

As a consequence of this view, I must also reach those subordinate issues not discussed by the majority. I would affirm the denial of summary judgment to the companies on the issue of the FDA's choice of the "combination-products" regulatory scheme. I believe,

however, that the district court erred in ruling that the FDA cannot, as a matter of statutory law, restrict the advertising of tobacco pursuant to the agency's authority to regulate the "sale" of such products.

I

When reviewing an agency's construction of a statute, we must first ask "whether Congress has directly spoken to the precise question at issue." *Chevron, U.S.A., Inc., v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842, 104 S. Ct. 2778, 81 L.Ed.2d 694 (1984). The usual rule is to enforce the plain language of a statute according to its terms. *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 241, 109 S. Ct. 1026, 103 L.Ed.2d 290 (1989). Whether the language is plain is "determined by reference to the language itself, the specific context in which the language is used, and the broader context of the statute as a whole." *Robinson v. Shell Oil Company*, 519 U.S. 337, 117 S. Ct. 843, 846, 136 L.Ed.2d 808 (1997). Here, the language is plain, and the context does not command a result contrary to the plain meaning.

The majority devotes approximately three paragraphs to the words that form the heart of the FDA's jurisdictional claim: "[T]he term 'drug' means . . . articles (other than food) intended to affect the structure or function of the body." 21 U.S.C. § 321(g)(1)(C). While as much as conceding that tobacco products fit the FDCA's "literal" definition of drug, the majority concentrates instead on what it believes is abundant evidence *elsewhere* demonstrating that Congress has never intended that tobacco come under FDA authority. Despite the apparent agreement about the "literal"

meaning of "drug" and "device," a few words are necessary to set the stage before moving on to a discussion of the "context" of the FDCA.

A

The rulemaking record contains voluminous evidence of the pharmacological effects of nicotine; in addition to being highly addictive, nicotine acts as a stimulant, tranquilizer and appetite suppressant. *See* 61 Fed.Reg. 44665-66 (1996). Under these assumed facts, nicotine clearly "affect[s] the structure or function of the body of man . . .", and I do not understand the majority to be saying otherwise. The only arguable impediment to a complete fit between the terms of the statute and tobacco products is the word "intended."

B

Building on the conclusion that the nicotine in tobacco products is highly addictive, the FDA proffered four independent rationales to satisfy the additional requirement that tobacco products be "intended" to affect the body: (1) a reasonable manufacturer would foresee that consumers would use the product to satisfy addiction, *see* 61 Fed. Reg. 44634, 44701-39; (2) most consumers do in fact use tobacco products to satisfy addiction, *see id.* at 44233; (3) the manufacturers have long known that consumers use the products for the pharmacological effects, *see id.* at 44849; and (4) the manufacturers design the products to deliver active doses of nicotine, *see id.* at 44951. On reasoning with which I agree, the district court held that the FDA could proffer evidence in support of the first and second of these rationales. *Coyne Beahm*, 966 F. Supp. at 1388-

92. In addition, I would also permit the use of recently disclosed evidence, including heretofore-secret company documents, that establish that the companies have known about the addictive qualities of their products for years and that cigarettes are deliberately manipulated to create and sustain addiction to nicotine.

My dictionary contains the following definitions of "intend": "1. To have in mind: PLAN. 2a. To design for a particular purpose. b. To have in mind for a particular purpose." WEBSTER'S II NEW RIVERSIDE UNIVERSITY DICTIONARY (1984). As a matter of simple English, the resultant effect on the body—nicotine addiction—is *intended* when the manufacturer (as we are assuming for the purposes of this appeal) deliberately designs the product to have that effect. This meaning is the primary, literal, and most common one attached to the word "intend," and it is ordinarily the one we should use. *See Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 187, 115 S. Ct. 788, 130 L.Ed.2d 682 (1995) ("When terms used in a statute are undefined, we give them their ordinary meaning."). The majority's argument does not convince me that we should abandon this common sense rule in this situation.

Prior to these rules, the FDA had "asserted jurisdiction over cigarettes only when health claims were made by the vendors or manufacturers." *Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 & n. 7 (D.C.Cir.1980) [hereinafter *ASH*] (citing as examples *United States v. 354 Bulk Cartons Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D.N.J.1959), in which cigarettes were marketed as weight reduction aids, and *United States v. 46 Cartons Fairfax Cigarettes*, 113 F.

Supp. 336 (D. N.J. 1953), in which cigarettes were marketed as helping to prevent respiratory diseases). No other court, however, has been confronted with the type and quantity of evidence collected during the rule-making process in this case; the strength of nicotine's addictive qualities, the extent of the health problems created by tobacco products, and the complicity of the manufacturers bring us to a different place than we have been before.

Products deliberately designed to create and sustain addiction are not likely to be marketed as such; indeed, such products are more likely listed elsewhere in Title 21 among the illegal controlled substances. It strikes me as patently absurd to contend that cigarettes and smokeless tobacco, products that are (under the assumed facts) actually designed to exert powerful and quintessentially drug-like effects on the users, should escape FDA regulation because the products are marketed as essential accoutrements of a more exciting or more sophisticated lifestyle.

II

Tobacco products, then, come squarely within the plain terms of the FDCA. If the words of a statute are plain, "absent any 'indication that doing so would frustrate Congress's clear intention or yield patent absurdity, our obligation is to apply the statute as Congress wrote it.'" *Hubbard v. United States*, 514 U.S. 695, 703, 115 S. Ct. 1754, 131 L.Ed.2d 779 (1995) (quoting *BFP v. Resolution Trust Corporation*, 511 U.S. 531, 570, 114 S. Ct. 1757, 128 L.Ed.2d 556 (1994) (Souter, J., dissenting)), *quoted in Dunn v. Commodity Futures Trading Commission*, 519 U.S. 465, 117 S. Ct.

913, 916, 137 L.Ed.2d 93 (1997). The questions, then, should be: Does upholding FDA jurisdiction over tobacco frustrate clear congressional intent to withhold such jurisdiction? Is it patently absurd? Does it "conflict with any other section of the Code, or with any important state or federal interest, [or] is a contrary view suggested by the legislative history[?]" *Ron Pair*, 489 U.S. at 243, 109 S. Ct. 1026. In other words, given the plain language used in § 321(g)(1)(C), the question should be whether the intent manifested by the words used—that tobacco products are "drugs [sic] delivery devices" subject to FDA regulation—is trumped by evidence to the contrary.

The majority seeks to show that the "context" of these readily understood words demonstrates that Congress really meant something else where tobacco is concerned. This search for context takes us into "the overall regulatory scheme created by Congress" (Maj. op. at 163) and "the history of evolving congressional regulation in the area" (Maj. op. at 162) (citation omitted), the legislative history of the FDCA and related statutes, and even congressional inaction. I will address each avenue explored by the majority.

A

The majority opens with this argument: The FDA's mandate is to prevent the marketing of any drug or device that is found to be unsafe; tobacco products are unsafe; to allow the continued sale of cigarettes is completely at odds with such mandate; *ergo*, the regulations must be struck down. But whether the regulations contravene the statute is a question wholly apart from whether *any* regulations could be issued. *How* the

FDA has chosen to regulate tobacco has no bearing on the question of *whether* that agency has the authority to regulate it at all, particularly when it is agreed that the power to regulate under the FDCA includes the power (under the assumed facts) to ban tobacco products completely. The FDA made an eminently reasonable decision to focus on preventing addiction among children while permitting sales to adults. *See* Fed. Reg. 44398-99, 44412-13. It is no argument to say that the FDA can do nothing because it could have done more.

B

The majority's analysis of the "extrinsic evidence" of congressional intent stands on three legs: The lack of any mention of tobacco in the statute itself or the legislative history of the 1938 Act; the FDA's consistent disavowal of any intention of taking jurisdiction over tobacco, and, concomitantly, the general assumption that the agency was right; and the series of tobacco-related statutes enacted over the last thirty years.[1]

The FDCA

In construing remedial legislation, we must be ever mindful of the salutary purpose of the statute.

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[1] As a corollary to this third point, the majority also relies on congressional *refusal* to enact legislation that would have expressly given the FDA the authority it now claims. *See* Maj. op. at 169-71. To whatever extent this inaction may be interpreted as "ratification" of the FDA's prior (no tobacco jurisdiction) position, it would appear that Congress's continued inaction in the face of all that has followed the FDA's announcement of the proposed rule three years ago (*see* 60 Fed. Reg. 41314) would more than offset any ratification effect to be gleaned from the earlier inaction.

> The historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show, we think, that Congress fully intended that the Act's coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow. [W]e are all the more convinced that we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health. . . .

United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 798, 89 S. Ct. 1410, 22 L.Ed.2d 726 (1969).[2] The majority starts off on the wrong foot when it asks "whether Congress intended to delegate jurisdiction over tobacco products to the FDA." Maj. op. at 162.

Congress did not "intend" that any particular product be included; as the district court noted, "[r]ather than itemize each product subject to regulation under the FDCA, Congress defined these categories broadly so that each encompasses a wide range of products."

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[2] Justice Frankfurter put it this way:

> The purposes of this legislation [FDCA] t[ou]ch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.

United States v. Dotterweich, 320 U.S. 277, 280, 64 S. Ct. 134, 88 L. Ed. 48 (1943).

Coyne Beahm v. FDA, 966 F.Supp. at 1380. An exhaustive list of covered products was neither feasible nor necessary; effective regulation required flexibility within broad parameters.

Pointing out the obvious—that the FDCA was not originally directed at tobacco—gets us nowhere. No one contends that Congress foresaw in 1938 that tobacco was or might someday be included as a "drug" under the FDCA. The operative congressional intent at the outset was simply to confer broad discretionary powers on the FDA to regulate "drugs" and "devices." The FDCA was written broadly enough to accommodate both new products and evolving knowledge about existing ones, and it was written that way on purpose.

FDA's Prior Position

Until the rulemaking began in 1995, the FDA had interpreted the FDCA to include tobacco products only when health claims were made. *See* Maj. op. at 168-69. The agency's refusal even extended to opposing citizens' petitions to regulate cigarettes on essentially the same basis that is used in the regulations today. *See, e.g., ASH*, 655 F.2d at 236. The agency's current position is a response to the increasing level of knowledge about the addictive nature of nicotine and the manufacturer's deliberate design to enhance and sustain the additive effect of tobacco products. When the early tobacco-specific statutes were being debated in Congress, the essential link between tobacco and illness had not yet been proven to the satisfaction of all. For instance, during the floor debate on amendments to the FCLAA, Rep. Perkins stated that

> [i]t is my feeling that not one of the tobacco farmers in my district would knowingly produce any commodity which, when consumed, would cause the dread diseases which have been claimed to be associated with tobacco. But the claims . . . are not proved. Tobacco has been impeached in passion but it had not been convicted in fact. Facts, cold hard facts are the basis upon which congress should legislate.

Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce, 91st Cong. 16 (1969). Well, the "cold hard facts" are now in.

It is a familiar canon of administrative law that an agency can change its view of what action is possible or necessary, particularly when new facts come to light. *See Rust v. Sullivan*, 500 U.S. 173, 186-87, 111 S. Ct. 1759, 114 L.Ed.2d 233 (1991) ("An agency . . . must be given latitude to adapt its rules and policies to the demands of changing circumstances") (citations and internal quotation marks omitted). Even when upholding the FDA's earlier denial of its own power to regulate tobacco, the court added the following caveat:

> Nothing in this opinion should suggest that the [FDA] is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch. An administrative agency is clearly free to revise its interpretations. . . . The very structure of the [FDCA] which the FDA must administer, moreover, calls for case-by-case analysis. Should an agency depart from its prior

> interpretations, however, it must provide a reasoned explanation for its action. . . . [citations omitted].

ASH, 655 F.2d at 242 n. 10.

Under the facts found by the FDA during the rulemaking process, it is now a scientific certainty that nicotine is extremely addictive and that a large majority of tobacco users use the product to satisfy that addiction; even more important to my mind is the new evidence that the manufacturers design their products to sustain such addiction. The administrative record in this case is a perfect illustration of why an agency's opportunity to adopt a new position should remain open.

The Tobacco Statutes

As products of the democratic process, each tobacco-specific statute is a balance of health, economic, and other concerns. The majority cites this body of legislation as "corroborating evidence of established congressional intent" to withhold jurisdiction over tobacco from the FDA. Maj. op. at 171. Again, I think the majority's approach ignores the fundamental source of intent, the words of the statute itself. Nevertheless, closer examination of these tobacco statutes reveals that they form something less than Congress's "comprehensive program" to address the tobacco problem. Absent a discernable intent to *exclude* future FDA action,[3] that these statutes were written with knowl-

[3] Congress certainly knows how to exempt tobacco. The only mention of tobacco in the FDCA was added in 1994 to explicitly

edge that the FDA forswore jurisdiction over tobacco does not supply that intent.

The first in this series, the Federal Cigarette Labeling and Advertising Act (FCLAA),[4] was enacted in response to the Surgeon General's ground-breaking 1964 report linking smoking to health problems. The companies describe it as a statute that "set the boundaries of the federal regulatory role," "clearly expresses a congressional intent that precludes FDA jurisdiction over tobacco products," "embodied the view that Congress, itself, should retain all policy making authority as to tobacco, even in areas open to regulation," "ratified the established understanding that FDA does not have jurisdiction over tobacco products," "ruled out any later reading of the FDCA as an 'implicit' delegation to FDA . . . of authority to decide whether or how to regulate tobacco products and whether to ban them." Companies' Opening br. 13, 18-20. An examination of the statute reveals something considerably more modest, something that will not bear anything approaching the weight placed upon it by the companies or the majority.

The majority's focus is § 1331, which reads:

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remove tobacco from the new exemption of "dietary supplements" from the definition of "drug." *See* Pub. L. No. 103-407, § 3(a), 108 Stat. 4325, 4327 (codified at 21 U.S.C. § 321(ff)). The criminal laws regarding narcotics incorporate the definition of "drug" found in the FDCA, *see* 21 U.S.C. § 802(12), but the definition of "controlled substance," which includes "a drug," specifically excludes tobacco. *See* 21 U.S.C. § 802(6).

[4] The Comprehensive Smokeless Tobacco Health and Education Act, 15 U.S.C. §§ 4401-4407, more or less mirrors the FCLAA.

> It is the policy of the Congress, and the purpose of this chapter, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby—
>
> (1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and
>
> (2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

This is a far cry from a comprehensive federal *tobacco* program; it is little more than a mild response to one of the earliest official recognitions of an emerging health issue.

The narrowness of the FCLAA was emphasized in *Banzhaf v. FCC*, 405 F.2d 1082 (D.C. Cir. 1968), where the court was confronted with a post-FCLAA ruling by the FCC that required radio and television stations that carried cigarette commercials to devote significant broadcast time to permit the case to be made against smoking. Then, as they do today, the tobacco companies argued that the FCLAA embodied a clear congressional intent to preclude intrusions into the regulation of tobacco by any agency. *See id.* at 1088. Judge Bazelon, however, saw things differently:

> [T]here are positive indications that Congress's "comprehensive program" was directed at the relatively narrow specific issue of regulation of "cigarette labeling and advertising." . . . Nothing in the [FCLAA] indicates that Congress had any intent at all with respect to other types of regulation by other agencies—much less that it specifically meant to foreclose all such regulation. If it meant to do anything so dramatic, it might reasonably be expected to have said so directly. . . .

Id. at 1089 (footnotes omitted) (quotations in original).[5] The next thirty years would see several more small steps that, even when considered together, fall far short of a comprehensive program, and even shorter of a demonstration that Congress intended to preclude the exercise of jurisdiction now being asserted by the FDA.

Following the FCLAA, the next step in what the companies characterize as Congress's ongoing program was the Public Health Cigarette Smoking Act of 1969, which amended the FCLAA in response to proposed incursions into the field by the FCC and FTC by way of proposed regulations that would have restricted tobacco advertising. Again, Congress addressed only advertising, this time in the electronic media, and short-circuited the roles proposed by the agencies for themselves.

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[5] In *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 514, 112 S. Ct. 2608, 120 L.Ed.2d 407 (1992), the Court described the purposes of the FCLAA as informing the public of the health risks and "protecting the national economy from the burden imposed by diverse, nonuniform, and confusing cigarette labeling advertising regulations" [footnote omitted].

Thirteen years later, Congress enacted the Alcohol and Drug Abuse Amendments of 1983, which simply directs the Secretary of HHS to report to Congress every three years on "the health consequences of drug abuse in the United States [and] current research findings made with respect to drug abuse, including current findings on . . . the addictive property of tobacco" and to include recommendations for "legislation and administrative action as the Secretary may deem appropriate." 42 U.S.C. § 290aa-2(b). This does not, as the majority asserts, "evidence[ ] Congress' . . . intent to retain control over further regulatory action." Maj. op. at 174. It is more an acknowledgment that because the HHS (and the FDA), as the experts in the complex field of drug abuse, had and would continue to have a crucial role to play, the Secretary was required to ask Congress for any *additional* tools it needed get to perform that role effectively.

The Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 [ADAMHA], the last brick in the purported congressional tobacco program, provides financial incentives to the States to enforce their own restrictions on access to tobacco by minors. The majority argues that the FDA regulations would conflict with this congressional determination that the States should take an active role in addressing the youth access problem because the FDCA preempts any different restrictions on devices. *See* 21 U.S.C. § 360k(a). This overstates the case.

ADAMHA restructured block grant programs aimed at substance abuse and mental health services; only a few provisions relate to underage smoking. *See* 42

U.S.C. § 300x-26. ADAMHA does not demonstrate an intent on Congress's part that the states "take the primary role" in addressing the problem of underage smoking, and it certainly does not "establish" a regulatory role for the states. Maj. op. at 175-76. Although the FDA's proposed regulations would preempt some state laws, the exercise of FDA authority over tobacco would not "prohibit the States from addressing the problem of youth access." *Id.* The proposed rule can co-exist with most of the states' separate laws prohibiting sales to minors and imposing other restrictions on tobacco sales. Even the few more stringent state or local restrictions that are preempted by the FDA's proposed regulations (*see* 61 Fed. Reg. 44548-50) might qualify for an exemption from preemption, thereby further minimizing conflicts. *See* 21 U.S.C. § 360k(b). An overlap between two regulatory systems does not require wholesale jettisoning of one in favor of the other. *See Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253, 112 S. Ct. 1146, 117 L.Ed.2d 391 (1992) ("Redundancies across statutes are not unusual events in drafting, and so long as there is no 'positive repugnancy' between two laws, a court must give effect to both") (internal citation omitted).

C

Tobacco *is* different from the articles commonly associated with the word "drugs," the FDA regulations are indeed the result of turnaround in agency thinking, and tobacco was most probably not on anyone's mind when the FDCA was enacted. But the FDCA was broadly worded by design. In an area in which complex new products (and old products, seen in the light of new evidence) pose the potential for grievous harm,

Congress deemed it necessary to delegate to an expert—the FDA—the job of monitoring drugs. Cigarettes and smokeless tobacco clearly fit within the literal terms of the FDCA. Absent a showing that following these statutory terms would be absurd or somehow frustrate congressional intent, we are bound to uphold FDA jurisdiction.

The FDA's denials that it had any authority over tobacco were certainly part of the background against which Congress passed tobacco-related legislation in the thirty years following the Surgeon General's 1964 report, but this series of statutes is hardly an argument for "legislative ratification" (Maj. op. at 170 n.18) of the FDA's prior position that the agency was powerless to act. It is agreed, moreover, that an agency is permitted to change its mind, particularly in response to new facts, so the real question is whether all that has gone before—the tobacco statutes, the consistent denials by the FDA—is sufficient to demonstrate a clear intent on Congress's part to *preclude* FDA jurisdiction. The evidence offered by the companies falls far short.

III

Having decided that the FDA has no jurisdiction over tobacco products, the majority had no reason to address whether cigarettes and smokeless tobacco were "devices" and whether the choice of regulatory regime—as a combination product, pursuant to the device authorities—was permissible. I agree with and adopt the district court's reasoning on these points entirely. *See Coyne Beahm*, 966 F. Supp. at 1393-97.

IV

Another issue not reached by the majority is whether the FDA may restrict the advertising of tobacco products.[6] On this point, I disagree with the district court's conclusion that the advertising regulations exceeded the FDA's statutory authority.

The FDA found that "cigarette and smokeless tobacco use begins almost exclusively in childhood and adolescence." 61 Fed.Reg. 45239. Minors are particularly vulnerable to Madison Avenue's exhortations, plastered on racing cars and outfield fences, to be cool and smoke, be manly and chew, and the FDA found "compelling evidence that promotional campaigns can be extremely effective in attracting young people to tobacco products." *Id.* at 45247.[7] The FDA chose to attack the problem by attempting to reduce the pressures to start using tobacco in the first place.

The pertinent portion of the of the 1976 Medical Device Amendments, 21 U.S.C. § 360j(e), provides:

> The Secretary may by regulation require that a device be restricted to sale, distribution, or use . . .

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[6] In view of its ruling on statutory grounds, it was unnecessary for the district court to reach the companies' constitutional objections to the advertising restrictions. *Coyne Beahm*, 966 F. Supp. at 1400 n. 33. Because neither party has briefed the First Amendment issue, I do not discuss it here.

[7] For example, one study cited in the rulemaking record found that "30% of 3-year-olds and 91% of 6-year-olds could identify Joe Camel as a symbol for smoking." *Id.* at 45246 (citing Fischer, Schwartz & Richards, *Brand Logo Recognition by Children Aged 3 to 6 Years, Mickey Mouse and Old Joe the Camel*, Journal of the American Medical Association, 1991).

> [by prescription] or upon such other conditions as the Secretary may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.

The FDA relies on this section as authority for the regulations restricting the advertising of tobacco products, its rationale being that the authority to restrict the "sale" of or to impose "other conditions" on a product includes within it the authority to restrict the means by which such sales are generated.

Examples of obviously permissible restrictions of the "sale" of a product are regulations regarding where, when, by whom, and to whom a product can be sold. But is a restriction on advertising a restriction of the "sale" of a product? The district court found that the plain meaning of the words precluded advertising restrictions: "Both as ordinarily defined and as used in the phrase 'may . . . be restricted to sale, distribution, or use,' the word 'sale' does not encompass the advertising or promotion of a product." *Coyne Beahm*, 966 F. Supp. at 1398 (footnote omitted). But even the dictionary entry cited in the district court's opinion defines "sale" as "the act of selling"; the term "sales" is defined as "[a]ctivities involved in the selling of goods and services." *Id.* at 174 n. 23. Under a *Chevron* step-two analysis—"if the statute is silent or ambiguous with respect to the specific issue, the question is whether the agency's answer is based on a permissible construction of the statute[,]" *Chevron*, 467 U.S. at 843, 104 S. Ct. 2778 (footnote omitted)—we need only find that the

agency construction is a reasonable one, not the best one. See *id.* at 163 n. 11. I believe the term "sale" is ambiguous enough to encompass the concept of "offer for sale."

The district court also distilled an intent to withhold the authority asserted by the FDA from the use of the terms "offer for sale" and "advertising" elsewhere in 1976 legislation. *See Coyne Beahm*, 966 F. Supp. at 1398-99. However, while the "language and design of the statute as a whole" (*K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291, 108 S. Ct. 1811, 100 L.Ed.2d 313 (1988)) might raise a question about the extent of the FDA's authority in this area, it does not mandate a conclusion that Congress intended to foreclose the FDA from imposing advertising restrictions. There is simply no conclusive evidence of intent either way; the phrase is simply ambiguous, both in isolation and with reference to the context in which it is used.

The term "sale, distribution and use," which is used only once in the entire FDCA, can reasonably be construed to include all aspects of a product's journey from the factory to the store and to the home. As I have noted above, tobacco is different from the run-of-the-mine drugs and devices in the FDA's bailiwick, and the nature of the differences dictate new approaches to fight the dangers posed. Because the precise approach chosen might not have been considered by the drafters of the statute does not necessarily preclude it. The interpretation is a reasonable one and, therefore, we must defer to the agency.

V

I would affirm the district court's judgment to the extent that it denies summary judgment to the tobacco companies on the issues of the FDA's authority to regulate tobacco products under the FDCA and to regulate such products as "combination products." I would vacate the judgment below to the extent it grants summary judgment to the companies on the issue of the FDA's authority to regulate the advertising of tobacco products.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
GREENSBORO DIVISION

Nos. 2:95CV00591, 2:95CV00593,
6:95CV00665 and 2:95CV00706

COYNE BEAHM, INC., BROWN & WILLIAMSON TOBACCO CORPORATION, LIGGETT GROUP, INC., LORILLARD TOBACCO COMPANY, PHILIP MORRIS, INCORPORATED, AND R.J. REYNOLDS TOBACCO COMPANY, PLAINTIFFS

v.

UNITED STATES FOOD & DRUG ADMINISTRATION AND DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD AND DRUGS, DEFENDANTS

AMERICAN ADVERTISING FEDERATION, AMERICAN ASSOCIATION OF ADVERTISING AGENCIES, INC., ASSOCIATION OF NATIONAL ADVERTISERS, INC., MAGAZINE PUBLISHERS OF AMERICA, OUTDOOR ADVERTISING ASSOCIATION OF AMERICA, POINT OF PURCHASE ADVERTISING INSTITUTE, PLAINTIFFS

v.

DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD AND DRUGS, AND UNITED STATES FOOD & DRUG ADMINISTRATION, DEFENDANTS

UNITED STATES TOBACCO COMPANY, BROWN & WILLIAMSON TOBACCO CORPORATION, CONWOOD COMPANY, L.P., NATIONAL TOBACCO COMPANY, L.P., THE PINKERTON TOBACCO COMPANY, SWISHER INTERNATIONAL, INC., CENTRAL CAROLINA GROCERS, INC., J.T. DAVENPORT, INC., N.C. TOBACCO DISTRIBUTORS COMMITTEE, INC., PLAINTIFFS

v.

UNITED STATES FOOD & DRUG ADMINISTRATION AND DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD AND DRUGS, DEFENDANTS

NATIONAL ASSOCIATION OF CONVENIENCE STORES, ACME RETAIL, INC., PLAINTIFFS

v.

DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD AND DRUGS, AND UNITED STATES FOOD & DRUG ADMINISTRATION, DEFENDANTS

[Filed: April 25, 1997]

MEMORANDUM OPINION

OSTEEN, District Judge.

This case comes before the court on Plaintiffs' Motion for Summary Judgment.[1] In August 1996, the Food

[1] For purposes of their motion for summary judgment, Plaintiffs do not dispute the finding of facts made in FDA's

and Drug Administration ("FDA") published in the *Federal Register* "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" ("Regulations"). 61 Fed. Reg. 44,396 (1996). Plaintiffs now seek summary judgment claiming that Congress has withheld the authority to regulate tobacco products as customarily marketed from FDA and that the Federal Food, Drug, and Cosmetic Act ("FDCA" or "Act")[2] does not authorize FDA to regulate tobacco products as "drugs" or "devices."

For the reasons discussed herein, Plaintiffs' Motion for Summary Judgment will be granted in part and denied in part.

I. DISCUSSION

A. SUMMARY JUDGMENT PRINCIPLES.

Summary judgment is appropriate in those cases where it is established through pleadings, affidavits, depositions, and other discovery documents that there exists no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48, 106 S. Ct. 2505, 2510, 91 L.Ed.2d 202

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jurisdictional determination and preamble to the Regulations. Although FDA did not formally move for summary judgment, it suggests in its Response Brief that the court can and should enter summary judgment in its favor. Since Plaintiffs would contest FDA's factual findings for purposes of a motion by FDA for summary judgment, summary judgment in favor of FDA would not be appropriate.

[2] 21 U.S.C. § 321 *et seq.*

(1986). Thus, it is the burden of the moving party to show the court that no material factual issues exist for trial. Of course, the court must draw any permissible inference from the underlying facts as established in the record in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88, 106 S. Ct. 1348, 1356-57, 89 L.Ed.2d 538 (1986); *Pulliam Inv. Co. v. Cameo Properties*, 810 F.2d 1282, 1286 (4th Cir.1987).

When the moving party has carried its burden, the nonmoving party must come forward with evidence which shows more than some "metaphysical doubt" that genuine and material factual issues exist. *Matsushita*, 475 U.S. at 586, 106 S. Ct. at 1356. A mere scintilla of evidence presented by the nonmoving party is insufficient to circumvent summary judgment. *Anderson*, 477 U.S. at 252, 106 S. Ct. at 2512. Rather, the nonmoving party must convince the court that, upon the record taken as a whole, a rational trier of fact could find for the nonmoving party. *Id.* at 248-49, 106 S. Ct. at 2510-11.

B. CONGRESS HAS NOT WITHHELD JURISDICTION TO REGULATE TOBACCO PRODUCTS FROM THE FOOD AND DRUG ADMINISTRATION.

Plaintiffs assert that Congress clearly intended to withhold jurisdiction to regulate tobacco products from FDA. Plaintiffs urge that the general structure and history of the FDCA and three federal statutes which address tobacco products reveal Congress' intent to reserve to itself the authority to shape federal policy regarding tobacco products and, moreover, that the

Regulations directly conflict with and are precluded by the three congressional tobacco-specific statutes.

The court reviews FDA's construction of the FDCA under the analysis set forth in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S. Ct. 2778, 81 L.Ed.2d 694 (1984). The first responsibility is to determine whether Congress has directly spoken to the precise question at issue for "[i]f the intent of Congress is clear, that is the end of the matter." *Id.* 467 U.S. at 842, 104 S. Ct. at 2781. If, however, the statute "is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* 467 U.S. at 843, 104 S. Ct. at 2782.

1. Congress Expressed No Clear Intent in the Federal Food, Drug, and Cosmetic Act to Withhold Jurisdiction to Regulate Tobacco Products from the Food and Drug Administration.

   a. The Text of the Federal Food, Drug, and Cosmetic Act.

The precise question presented to the court is whether Congress has evidenced its clear intent to withhold from FDA jurisdiction to regulate tobacco products as customarily marketed.[3] The inquiry as to

[3] Plaintiffs do not dispute that FDA has authority to regulate tobacco products marketed as providing medical or other health benefits. *See United States v. 354 Bulk Cartons Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D.N.J.1959) (manufacturer claimed in display cards, circulars, and point-of-sale materials that its brand was effective for weight reduction); *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336 (D.N.J. 1953) (manufacturer promoted the cigarettes through leaflets as effective in preventing certain diseases).

whether Congress has directly spoken to the issue should begin with an examination of the text of the FDCA.[4] *Mead Corp. v. Tilley*, 490 U.S. 714, 722, 109 S. Ct. 2156, 2162, 104 L.Ed.2d 796 (1989); *Kofa v. INS*, 60 F.3d 1084, 1088 (4th Cir. 1995). A product is subject to the FDCA if it meets the statute's definition of a "food," "drug," "device," or "cosmetic." *See* 21 U.S.C. § 321. Rather than itemize each product subject to regulation under the FDCA, Congress defined these categories broadly so that each encompasses a wide range of products.

As will be discussed more fully regarding the second issue raised by Plaintiffs, the court finds that tobacco products fit within the FDCA's definitions of "drug" and "device." Therefore, Plaintiffs must prove to the court that Congress has expressed its clear intent to withhold from FDA jurisdiction to regulate tobacco products in some place other than the text of the FDCA.

[4] In support of their assertion that Congress has clearly withheld from FDA jurisdiction over tobacco products, Plaintiffs devote only a small portion of their brief to an examination of the text of the FDCA. Plaintiffs contend that neither the text of the FDCA nor its direct legislative history addresses tobacco products and that the court should, therefore, focus its inquiry on federal legislation that specifically addresses tobacco products. The court will instead first examine the text and legislative history of the FDCA.

b. The Legislative History of the Federal Food, Drug, and Cosmetic Act.

Both parties find support for their arguments in the FDCA's legislative history. Plaintiffs first note that tobacco products not only were highly visible in the years preceding passage of the FDCA, but also were recognized by the federal government as a separate sector of the economy. (Pls.' First Br. Supp. Mot. Summ. J. at 8-9.) Plaintiffs contend that had Congress meant to place such highly visible and controversial products within FDA's jurisdiction, the legislative history of the FDCA would reveal some discussion of the matter. FDA, on the other hand, argues that in its enactment of the FDCA in 1938, Congress broadened the scope of the previous food and drug law, and, despite the high visibility of tobacco products, never excluded them from the FDCA's reach.

Congress passed the first food and drug law, the Pure Food and Drugs Act, in 1906. Pub.L. No. 59-384, 34 Stat. 768 (1906). The 1906 Act defined "drug" to include "all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substances or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals." *Id.* In 1938, Congress passed the FDCA and expanded the definition of "drug" to include articles "intended to affect the structure or function of the body." 21 U.S.C. § 321(g)(1)(C). The House Report accompanying the FDCA explained that the expansion of the definition of "drug" was intended to "amplif[y] and strengthen[ ]" the FDCA. H.R. Rep. No. 75-2139, at 2 (1938).

In addition to expanding the definition of "drug," Congress added the "device" category to the FDCA in 1938 and included within its definition "instrument[s], apparatus, implement[s], machine[s], contrivance[s], . . . including any component, part, or accessory . . . intended to affect the structure or any function of the body." 21 U.S.C. § 321(h)(3). Congress determined that the "expansion of the definition of the term 'drug' and the inclusion of devices are essential if the consumer is to be protected against a multiplicity of abuses not subject to the present law." S. Rep. No. 74-646, at 1 (1935). Thus Congress, intending to expand the scope of the federal food and drug laws, broadly defined the categories of products to which the FDCA would apply.

In their examination of the legislative history of the FDCA, Plaintiffs focus on the absence of any discussion of tobacco products and assert that although Congress was aware of the possibility of extending FDA's jurisdiction to reach tobacco products, it chose not to. Plaintiffs note that in 1914, FDA's predecessor agency, the Bureau of Chemistry in the Department of Agriculture, expressed its view that it could not regulate tobacco products as customarily marketed under the 1906 Act. Bureau of Chemistry, U.S. Department of Agriculture, *Service & Regulatory Announcements*, No. 13 (Apr. 2, 1914). Plaintiffs also note that in 1929, legislation which would have amended the 1906 Act to cover tobacco products was introduced and referred to the committee on Agriculture and Forestry, but never passed. S. 1468, 71st Cong. (1929). Thus, Plaintiffs contend that Congress was aware of both the highly visible tobacco products and of the possibility of extending jurisdiction under the food and drug laws to cover tobacco products. Plaintiffs conclude that had

Congress contemplated placing tobacco products within the reach of the FDCA, there would have been opposition to, or, at the very least, discussion of the matter. (Pls.' First Br. Supp. Mot. Summ. J. at 9, n. 9.)

The legislative history's silence regarding tobacco products does not indicate that Congress clearly intended to exempt such products from the Act. The FDCA applies to any product which meets one of the broad definitions of the Act, and the absence of discussion of the Act's application to even a highly visible product does not foreclose regulation of that product under the Act. This court is convinced that neither the text nor the legislative history of the FDCA evidences clear congressional intent to withhold from FDA authority to regulate tobacco products.

c. The Food and Drug Administration's Representations to Congress, Statements of Members of Congress, and Unenacted Legislation.

Plaintiffs contend that FDA's past representations to Congress, the remarks of certain members of Congress, and a series of unenacted bills reveal not only that Congress believed that FDA lacked authority to regulate tobacco products, but also that Congress acquiesced to and ratified that position.

FDA officials testified before congressional committees on numerous occasions that the agency lacked jurisdiction to regulate tobacco products. For example, FDA informed Congress in 1963 that tobacco products as customarily marketed did not meet the definitions in the FDCA for food, drug, device, or cosmetic. *See* Letter from FDA Bureau of Enforcement (May 23,

1963), *reprinted in Hearings Before the Consumer Subcomm. of the Senate Comm. on Commerce on S. 1454*, 92d Cong., 2d Sess. 240 (1972) ("*1972 Hearings*"). In 1965, an FDA official testified at a congressional hearing that FDA "has no jurisdiction under the [FDCA] over tobacco, unless it bears drug claims." *Cigarette Labeling and Advertising, Hearing Before the House Comm. on Interstate and Foreign Commerce on H.R. 2248*, 89th Cong. 193 (1965). In 1972, FDA Commissioner Charles Edwards testified that although cigarettes and other tobacco products would be drugs within the meaning of the FDCA if medical claims were made for them, "cigarettes recommended for smoking pleasure are beyond the [FDCA]." *1972 Hearings* at 239. In 1989, FDA Commissioner Frank Young once again conveyed to Congress that "it doesn't look like it is possible to regulate [tobacco] under the [FDCA] even though smoking, I think, has been widely recognized as being harmful to human health." *Hearing Before the Subcomm. on Rural Development, Agriculture, and Related Agencies of the House Comm. on Appropriations*, 100th Cong. 409 (1989).

In addition to expressing its view to Congress that it lacked jurisdiction to regulate tobacco products, FDA defended that position in court. In May 1977, an anti-tobacco group, Action on Smoking and Health ("ASH"), petitioned FDA to regulate cigarettes as "drugs." *Citizen Petition*, Dkt. No. 77P-0185 at 4-11 (May 26, 1977). FDA rejected ASH's petition and the circuit court upheld FDA's decision. *See ASH v. Harris*, 655 F.2d 236 (D.C.Cir.1980). One year later, ASH petitioned FDA to regulate cigarettes as "devices," *Citizen Petition*, Dkt. No. 78P-0338 (Oct. 2, 1978), and FDA rejected ASH's petition. Letter from Acting Com-

missioner Mark Novitch for Commissioner of Food and Drugs to John F. Banzhaf, III, at 3 (November 25, 1980), Dkt. Nos. 77P-0185, 78P-0338/CP.

There is little question that members of Congress agreed with FDA's assertions that it lacked jurisdiction and, in an effort to remedy the situation, introduced numerous bills which would have expressly granted FDA authority to regulate tobacco products. None of the bills passed. *See, e.g.*, H.R. 11280, 84th Cong. (1956); S. 2554, 85th Cong. (1957); H.R. 592, 85th Cong. (1957); S. 1682, 88th Cong. (1963); H.R. 5973, 88th Cong. (1963); H.R. 9512, 88th Cong. (1963); H.R. 2248, 89th Cong. (1965); H.R. 2419, 95th Cong. (1977); H.R. 3879, 95th Cong. (1977); H.R. 7168, 95th Cong. (1977); S. 3317, 95th Cong. (1978); H.R. 279, 96th Cong. (1979); H.R. 3294, 99th Cong. (1987); H.R. 1494, 100th Cong. (1989); S. 769, 100th Cong. (1989). In introducing many of these bills, members of Congress stated that the legislation was needed to give FDA jurisdiction to regulate tobacco products.

Thus, there is evidence not only that FDA previously asserted that it lacked jurisdiction to regulate tobacco products as customarily marketed, but also that some members of Congress agreed with FDA and introduced legislation to expressly grant FDA jurisdiction. Plaintiffs conclude that Congress believed FDA lacked jurisdiction and that its rejection of bills designed to expressly grant FDA such jurisdiction, its amendment of the FDCA without granting such jurisdiction, and its enactment of other tobacco-specific legislation reveal that Congress acquiesced to and ratified FDA's assertion of lack of jurisdiction. The court must first determine whether Congress acquiesced to or ratified FDA's

previous assertions of lack of authority, and, if the court finds that Congress did, determine whether FDA permissibly adapted its position to new evidence.

i. Congress Neither Acquiesced to Nor Ratified the Food and Drug Administration's Position.

The Supreme Court has recognized that unenacted bills generally provide rather unpersuasive evidence of congressional intent. *See Central Bank of Denver v. First Interstate Bank of Denver*, 511 U.S. 164, 187, 114 S. Ct. 1439, 1453, 128 L.Ed.2d 119 (1994) ("[F]ailed legislative proposals are a particularly dangerous ground on which to rest an interpretation of a prior statute.") (internal citations omitted). Further, "the interpretation given by one Congress (or a committee or member thereof) to an earlier statute is of little assistance in discerning the meaning of that statute." *Id.* at 185, 114 S. Ct. at 1452 (quoting *Public Employees Retirement Sys. of Ohio v. Betts*, 492 U.S. 158, 168, 109 S. Ct. 2854, 2861, 106 L.Ed.2d 134 (1989)).

Despite its general reluctance to rely on unenacted bills and statements by members of Congress as evidence of congressional intent, the Supreme Court has held that the rejection of bills by Congress may be relevant to a determination of congressional intent where there are extraordinary circumstances. *See Bob Jones University v. United States*, 461 U.S. 574, 600-02, 103 S. Ct. 2017, 2032-34, 76 L.Ed.2d 157 (1983) (Where "exhaustive hearings" were held on specific issue and "no fewer than 13 bills introduced," Congress' "failure to act" was relevant.); *United States v. Riverside Bayview Homes, Inc.*, 474 U.S. 121, 137, 106 S. Ct. 455, 464, 88 L.Ed.2d 419 (1985) (Congress' failure to act is

relevant "particularly where the administrative construction has been brought to Congress' attention through legislation specifically designed to supplant it."). Plaintiffs contend that FDA's previous assertions that it lacked jurisdiction, Congress' rejection of legislation designed to grant FDA jurisdiction, and the belief of some members of Congress that FDA lacked jurisdiction are extraordinary circumstances which are relevant to a determination of congressional intent. The court is persuaded that the circumstances presented fall short of the extraordinary circumstances found in *Riverside Bayview Homes* and *Bob Jones University*.

In *Riverside Bayview Homes*, the Army Corps of Engineers exercised jurisdiction over wetlands pursuant to the Clean Water Act. Soon thereafter, while considering amendments to the Clean Water Act, Congress specifically considered the regulations. After lengthy debates in both chambers regarding the Corps' assertion of jurisdiction, the Senate version, which did not deny the Corps jurisdiction over wetlands, passed. The House version, however, which denied the Corps jurisdiction, failed to pass. The Court noted that although it would not usually attribute significance to Congress' failure to act, a refusal by Congress to overrule agency construction of a statute, particularly where that construction was brought to the attention of Congress by means of legislation specifically designed to supplant it, was persuasive.

In *Bob Jones University*, the Supreme Court upheld a challenged Internal Revenue Service ("IRS") ruling. Noting congressional failure to modify the ruling despite full awareness of it and refusal to pass 13 bills

which had been introduced to reverse the ruling, the Court stated that Congress had done more than merely fail to act on legislative proposals and had actually acquiesced to the IRS's interpretation. The Court also noted that Congress had affirmatively manifested acquiescence to the policy when it reenacted a version of the section at issue without altering the position taken by the IRS.

Both *Riverside Bayview Homes* and *Bob Jones University* are distinguishable from this case. First, the regulations at issue in *Riverside Bayview Homes* generated a greater response in Congress than did any of FDA's assertions of lack of jurisdiction. Specifically, in *Riverside Bayview Homes*, Congress rejected legislation that would have altered the Corps' regulations and passed legislation that did not alter those regulations only after extensive debate in both chambers. In this case, of the numerous bills introduced to grant FDA jurisdiction over tobacco products, none were reported out of committee. (Defs.' Br. Opp'n Mot. Summ. J. at 36.) Moreover, both *Riverside Bayview Homes* and *Bob Jones University* involved congressional consideration not of an agency's assertion of inability to act, but of agency action. Thus, in both *Riverside Bayview Homes* and *Bob Jones University*, the agency took action,[5] Congress subsequently considered the matter, and ultimately decided not to invalidate the agency action. In this case, Plaintiffs

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[5] The Army Corps of Engineers promulgated regulations in *United States v. Riverside Bayview Homes, Inc.*, 474 U.S. 121, 106 S. Ct. 455, 88 L.Ed.2d 419 (1985), and the Internal Revenue Service issued rulings in *Bob Jones University v. United States*, 461 U.S. 574, 103 S. Ct. 2017, 76 L.Ed.2d 157 (1983).

urge the court to find that Congress acquiesced not to agency action, but rather to assertions by an agency that it lacked power to act. No case finding congressional acquiescence after an agency's assertion of lack of jurisdiction to act has been cited to the court. The acquiescence argument is less persuasive in this context.

Even if Congress acquiesced to or ratified FDA's prior position that it lacked jurisdiction to regulate tobacco products, the Supreme Court has held that congressional acquiescence to or ratification of agency policy would not necessarily connote approval or disapproval of the agency's later alteration of that policy. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 45, 103 S. Ct. 2856, 2867-68, 77 L.Ed.2d 443 (1983) ("While an agency's interpretation of a statute may be confirmed or ratified by subsequent congressional failure to change that interpretation, . . . even an unequivocal ratification—short of statutory incorporation—of the [agency's interpretation] would not connote approval or disapproval of an agency's later decision to [alter that interpretation]."). Even if Congress acquiesced to FDA's assertion of lack of jurisdiction, such acquiescence would not necessarily connote Congress' opposition to FDA's assertion of jurisdiction.

ii. The Food and Drug Administration May Adapt its Position to New Evidence.

The Supreme Court has held that an agency is entitled to adapt its policies. *See Chevron*, 467 U.S. at 863-64, 104 S. Ct. at 2792 ("An initial agency interpretation is not instantly carved in stone. On the

contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis."). For example, in *Motor Vehicle Mfrs. Ass'n*, 463 U.S. 29, 103 S. Ct. 2856, 77 L.Ed.2d 443, the Court reviewed the Secretary of Transportation's rescission of a requirement that automobiles be equipped with passive restraint systems and held that previous congressional support for the passive restraint requirement did not preclude a change in policy. The Court noted that it "fully recognize[d] that regulatory agencies do not establish rules of conduct to last forever" and that "an agency must be given ample latitude to adapt [its] rules and policies to the demands of changing circumstances." *Id.* at 42, 103 S. Ct. at 2866 (internal citations omitted); *see also Rust v. Sullivan*, 500 U.S. 173, 111 S. Ct. 1759, 114 L.Ed.2d 233 (1991) (Noting that an agency may revise a previous interpretation, the Court rejected the plaintiffs' argument that the challenged regulations were not entitled to deference under the second prong of *Chevron* analysis because they reversed the agency's longstanding interpretation of the statute.); *ASH*, 655 F.2d 236, 242 n. 10 (D.C.Cir.1980) (The court noted, in upholding FDA's denial of jurisdiction to regulate cigarettes, that "[n]othing in this opinion should suggest that [FDA] is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch. An administrative agency is clearly free to revise its interpretations.").

FDA contends that it has not altered its interpretation of the FDCA but rather has applied its longstanding interpretation to new evidence. As more fully addressed in the court's discussion of the second issue raised by Plaintiffs, the court finds FDA's contention to

be reasonable. *Chevron*, *Motor Vehicle Mfrs. Ass'n*, and *Rust* support the finding that FDA is entitled to adapt its position in light of new evidence.

Thus, the text of the FDCA, its legislative history, and the body of evidence consisting of FDA's representations to Congress, unenacted bills, and statements by members of Congress do not clearly indicate that Congress intended to withhold from FDA the authority to regulate tobacco products.

2. Congress' Tobacco-Specific Legislation Does Not Reveal that Congress Intended to Withhold Jurisdiction to Regulate Tobacco Products from the Food and Drug Administration.

Plaintiffs assert that Congress has reserved to itself the authority to set federal policy regarding tobacco products. Plaintiffs explain that the structure and history of the Federal Cigarette Labeling and Advertising Act ("FCLAA"),[6] the Comprehensive Smokeless Tobacco Health Education Act ("CSTHEA"),[7] and the Alcohol, Drug Abuse, and Mental Health Reorganization Act of 1992 ("ADAMHA Amendments")[8] reveal Congress' clear intent on the matter. Plaintiffs further urge that conflict between the Regulations and Congress' tobacco-specific legislation supports their argument that Congress clearly reserved to itself the authority to regulate tobacco products. Each statute must be separately addressed.

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6 15 U.S.C. §§ 1331-40.

7 15 U.S.C. §§ 4401-08.

8 42 U.S.C. § 300x-26.

a. The Federal Cigarette Labeling and Advertising Act.

Plaintiffs' position is that Congress, believing that FDA lacked jurisdiction to regulate tobacco products, decided to address the concerns raised by tobacco use. Plaintiffs further assert that Congress, in enacting and later amending the FCLAA, expressed its clear intent to shape federal policy regarding tobacco products and to deny FDA a role in implementing that policy. The FCLAA's declaration of policy and purpose states:

> It is the policy of Congress, and the purpose of this chapter, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby—
>
> (1) the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes; and
>
> (2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

15 U.S.C. § 1331. Plaintiffs conclude that this statement of policy evidences Congress' intent to set all federal policy regarding cigarette labeling and advertising.

From a review of only the FCLAA's statement of policy and purpose, Congress arguably intended to preempt any regulation of tobacco products not specifically ordered by Congress. Yet Congress drafted the FCLAA's separate preemption provision very narrowly so as to provide, in relevant part, only that "[n]o statement relating to smoking and health, other than the statement required by section 1333 of this title, shall be required on any cigarette package." 15 U.S.C. § 1334.[9]

The relatively narrow preemptive scope of § 1334 precludes a finding that Congress intended to reserve to itself alone the power to regulate tobacco products. Although § 1331 states that the FCLAA is designed to establish a comprehensive federal program, Congress did not expressly preclude other regulation of tobacco products in § 1334. "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517, 112 S. Ct. 2608, 2618, 120 L.Ed.2d 407 (1992) (discussing preemptive scope of § 1334(b), which addresses federal preemption of state law).

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[9] The court acknowledges that federal-state preemption law does not directly govern the issue of FDA's jurisdiction to regulate tobacco products. Nevertheless, principles from federal-state preemption law apply to the issue of whether Congress has forbidden FDA from regulating tobacco products. Indeed, both the FCLAA and the CSTHEA contain "preemption" sections which specifically address the authority of federal agencies to regulate both cigarettes and smokeless tobacco products, respectively. See 15 U.S.C. §§ 1334, 4406.

Plaintiffs also assert that portions of the FCLAA directly conflict with FDA's assertion of authority. Specifically, Plaintiffs assert that the FCLAA conflicts with the Regulations in the following areas. First, they say that Congress currently permits the manufacture and sale of cigarettes that comply with the FCLAA, and conclude from that fact that Congress in the FCLAA decided that print advertising of tobacco products "should remain lawful, so long as it carries the congressionally-mandated warnings." (Pls.' First Br. Supp. Mot. Summ. J. at 32.) Such conclusion is unwarranted. The fact that Congress has up to this date allowed the manufacture and sale of cigarettes that carry the required warnings does not clearly demonstrate that Congress has determined that no other requirements may be imposed. Congress crafted narrow preemption language in the FCLAA which does not evidence an intention to preclude other regulation of tobacco products. FDA's restrictions on advertising and promotion do not conflict with either the language or the purpose of the FCLAA.

Second, Plaintiffs assert that the Regulations' requirement that cigarette packages state the "established name" of the product (e.g., "cigarette," "cigarette tobacco") and bear the statement "Nicotine-Delivery Device for Persons 18 or Older" is expressly preempted by the FCLAA. FDA agrees that the FCLAA prohibits FDA from requiring packages or advertisements to carry any statement related to smoking and health. FDA argues, however, that the inclusion of the established name merely provides basic information to those coming into contact with the product and that the statement of intended use merely advises consumers about the product's intended use.

According to FDA, neither statement relates to smoking and health within the meaning of § 1334 because neither qualifies as a cautionary statement and that, therefore, neither statement is preempted by the FCLAA.

The Supreme Court addressed the preemptive scope of the FCLAA in *Cipollone*, 505 U.S. 504, 112 S. Ct. 2608, 120 L.Ed.2d 407 (1992). The Court was faced in part with the issue of whether the FCLAA preempted state common law claims of failure to warn. The Court stated that the phrase "No statement relating to smoking and health"

> referred to the sort of warning provided for in [§ 1333], which set forth verbatim the warning Congress determined to be appropriate. Thus, on their face, these provisions merely prohibited state and federal rule-making bodies from mandating particular cautionary statements on cigarette labels . . . or in cigarette advertisements. . . .

Id. at 518, 112 S. Ct. at 2618.[10] Neither the statement of intended use nor the established name required by the Regulations is a particular cautionary statement of the type required in § 1333. Thus, neither is expressly preempted by the FCLAA.

The Regulations do not conflict with the text of the FCLAA, and the general structure and purpose of the FCLAA do not evidence Congress' clear intent to

[10] Section 1334(b), rather than § 1334(a), was at issue in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S. Ct. 2608, 120 L.Ed.2d 407 (1992). Nonetheless, the Court's analysis is applicable because the relevant language in the two sections is the same.

withhold jurisdiction from FDA to regulate tobacco products.

b. The Comprehensive Smokeless Tobacco Health Education Act.

Plaintiffs assert that Congress, when it passed the CSTHEA in 1986, reserved to itself the authority to set federal policy regarding smokeless tobacco products. The CSTHEA, like the FCLAA, contains a relatively narrow preemption provision, which provides in relevant part that:

> (a) Federal action
>
> No statement relating to the use of smokeless tobacco products and health, other than the statements required by section 4402 of this title, shall be required by any Federal agency to appear on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.

15 U.S.C. § 4406. Thus, although the CSTHEA is entitled the *Comprehensive* Smokeless Tobacco Health Education Act, and although Congress addressed in the CSTHEA several of the concerns addressed by FDA in the Regulations, the court finds that Congress did not intend to reserve to itself the exclusive authority to regulate smokeless tobacco products. Rather, the preemptive scope of the CSTHEA is defined by § 4406 because "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." *Cipollone*, 505 U.S. at 517, 112 S. Ct. at 2618. The narrow effect of

§ 4406 precludes a finding that Congress intended that the CSTHEA preclude all FDA regulation of smokeless tobacco products.

Plaintiffs urge that the CSTHEA expressly preempts the Regulations. Specifically, they contend that FDA's requirement that tobacco products bear a statement of intended use is preempted because the statement relates to the use of smokeless tobacco products and health. The preemption clause of the CSTHEA, like that of the FCLAA, does not preempt FDA's requirement that tobacco products bear both a statement of intended use and the established name of the product.

Thus, the Regulations do not conflict with the text of the CSTHEA, and the general structure and purpose of the CSTHEA do not evidence Congress' clear intent to withhold from FDA jurisdiction to regulate tobacco products.

c. The Alcohol, Drug Abuse, and Mental Health Reorganization Act of 1992.

Plaintiffs assert that Congress' enactment of the ADAMHA Amendments in 1992 evidences Congress' intent to deny FDA jurisdiction over tobacco products. The ADAMHA Amendments withhold federal substance abuse block grants from states that fail to enact and enforce laws prohibiting tobacco sales to minors. Plaintiffs contend that in enacting the ADAMHA Amendments, Congress determined that the initiative for addressing youth access to tobacco products should remain at the state level, and that the appropriate federal role in tackling youth access to tobacco products

is to encourage and help the states in the implementation and enforcement of state policy regarding tobacco products. Plaintiffs further assert that FDA's national program conflicts directly with what Plaintiffs contend is the thrust of the ADAMHA Amendments, which is to place the initiative for development of regulations addressing youth access to tobacco products at state level.

Plaintiffs find that the conflict between the ADAMHA Amendments and the Regulations is clearly demonstrated by the FDCA's preemption provision, which preempts the states from imposing on devices "requirements" that are different from or in addition to those imposed by FDA. 21 U.S.C. § 360k. The argument proceeds that if the FDCA applies to tobacco products, § 360k would prohibit states from addressing the issue of youth access. FDA responds that the Regulations will not affect many aspects of state regulation of underage smoking and that states may qualify for exemptions from the Regulations pursuant to 21 U.S.C. § 360k(b). The Regulations will not prevent states from separately enforcing their own laws regarding underage access or from imposing other restrictions on the access to tobacco products.

Finally, Plaintiffs find in the ADAMHA Amendments a congressional statement of policy regarding tobacco products that is not apparent to the court. The ADAMHA Amendments restructured several federal substance abuse and mental health programs to create two block grants, one directed to drug and alcohol abuse programs, and the other to community mental health services. To receive funds under the substance abuse block grant program, states must conform to a

number of conditions, only a few of which relate to the availability of tobacco products to children under the age of 18.[11] The ADAMHA Amendments merely establish conditions for the receipt of federal funds and do not represent an all-encompassing last-word pronouncement of federal policy on underage smoking. The discretionary block grant scheme established by the ADAMHA Amendments does not impliedly preclude further federal requirements regarding tobacco products. Therefore, the court finds that the Regulations conflict with neither the text nor the structure of the ADAMHA Amendments.

Plaintiffs would have the court find from the structure, history, and specific provisions of the FCLAA, the CSTHEA, and the ADAMHA Amendments that Congress clearly intended to reserve to itself, and to withhold from FDA, jurisdiction to regulate tobacco products. Further, Plaintiffs say that the three statutes, working together, comprise Congress' comprehensive policy regarding tobacco products. These conclusions are not justified. Congress, in enacting and later amending the three statutes, adopted narrow preemption language, evidencing its intent not to prohibit other agency action in the area. Moreover, the court cannot find, as Plaintiffs urge, that the three

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[11] The conditions relating to underage access restrictions provide that states must: (i) prohibit sales to children under 18; (ii) enforce that prohibition "in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18"; (iii) conduct annual random, unannounced inspections of tobacco retailers; and (iv) make annual reports to the Department of Health and Human Services concerning the method and effects of the state enforcement efforts. 42 U.S.C. § 300x-26.

statutes, construed together, evidence Congress' clear intent to withhold from FDA jurisdiction to regulate tobacco products.[12]

In conclusion, the FDCA, the FCLAA, the CSTHEA, and the ADAMHA Amendments do not reveal that Congress clearly intended to withhold from FDA authority to regulate tobacco products.

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[12] The court is not presented with a situation similar to that in *International Bhd. of Teamsters v. Daniel*, 439 U.S. 551, 99 S. Ct. 790, 58 L.Ed.2d 808 (1979). The issue in *International Bhd. of Teamsters* was whether the Securities Exchange Act ("SEA"), as asserted by the Securities and Exchange Commission ("SEC"), appearing as *amicus*, applied to noncontributory compulsory pension plans. The Court noted that the Employee Retirement Income Security Act ("ERISA"), which was enacted after the SEA, constituted comprehensive legislation governing the use and terms of employee pension plans and found that Congress had enacted ERISA in order to fill the regulatory gap that had been created regarding pension plans. The Court noted that SEC had never before interpreted the SEA to apply to noncontributory compulsory pension plans and found that SEC's new interpretation was precluded by the later comprehensive ERISA. As explained above, the FCLAA, the CSTHEA, and the ADAMHA Amendments, unlike ERISA, do not create a comprehensive federal approach to the regulation of tobacco products, making this case distinguishable from *International Bhd. of Teamsters*.

C. THE FOOD AND DRUG ADMINISTRATION MAY REGULATE TOBACCO PRODUCTS PURSUANT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

Plaintiffs assert that tobacco products do not fall within the FDCA's definitions of "drug" and "device." Plaintiffs further assert that FDA misapplied the provisions of the FDCA to tobacco products, and that FDA's misapplication of the Act further demonstrates that FDA lacks jurisdiction to regulate tobacco products under the FDCA. The court's responsibility is to determine whether tobacco products fit within the FDCA's definitions of "drug" and "device" and then to examine FDA's application of the Act to tobacco products.

1. Tobacco Products Fall Within the "Drug" and "Device" Definitions of the Federal Food, Drug, and Cosmetic Act.

The FDCA defines "drug" and "device," in relevant part, as follows:

> The term "drug" means . . . (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals.
>
> 21 U.S.C. § 321(g)(1).

> The term "device" . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
>
> . . . .
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.
>
> 21 U.S.C. § 321(h).[13]

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[13] The court will refer to §§ 321(g)(1)(C) and (h)(3) as the "structure-or-function" definitions of "drug" and "device," respectively, and to §§ 321(g)(1)(B) and (h)(2) as the "treatment-of-disease" definitions of "drug" and "device," respectively. The court includes the treatment-of-disease definition because of its relevance to the court's discussion of the meaning of intended use. Specifically, since both definitions refer to the intended use of a product, both are relevant to the court's interpretation of the phrase.

FDA offers that tobacco products fall within the FDCA's definitions of "drugs" and "devices" because they are "intended to affect the structure or any function of the body." FDA explains that the nicotine in tobacco products affects the structure or function of the body by causing and sustaining addiction and by acting as a stimulant, sedative, and weight regulator. FDA further argues that manufacturers intend nicotine to produce such effects. Plaintiffs disagree, claiming that tobacco products neither "affect the structure or any function of the body" nor are intended to affect the structure or function of the body within the meaning of the FDCA.

a. Tobacco Products' Effects are "Intended" Within the Meaning of the Federal Food, Drug, and Cosmetic Act.

Plaintiffs claim that a product's "intended use" can be established only by manufacturer representations about the product.[14] FDA counters that it appropriately relied on evidence of foreseeability, consumer use, and internal manufacturer memoranda to establish intended use. The text, legislative history, and past judicial and agency interpretation of the structure-or-function definitions of "drug" and "device" reveal that intended use may be established by evidence other than manufacturer representations.

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[14] FDA does not contend that tobacco manufacturers make any representations in connection with the sale of tobacco products. Therefore, if intended use can be established only by manufacturer representations, tobacco products would not be subject to regulation pursuant to the FDCA.

Since the FDCA does not define "intend," the court must give the term its ordinary meaning. *See Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 187, 115 S. Ct. 788, 793, 130 L.Ed.2d 682 (1995) ("When terms used in a statute are undefined, we give them their ordinary meaning."). FDA directs the court to two definitional sources. First, a dictionary defines "intend" as "[t]o have in mind; plan.... [t]o design for a specific purpose. . . . [t]o have in mind for a particular use." *The American Heritage Dictionary* 668 (2d ed.1991). Second, according to FDA, the court should consider the legal usage of "intend," which includes the principle that one intends the readily foreseeable consequences of his actions. *See Agnew v. United States*, 165 U.S. 36, 53, 17 S. Ct. 235, 242, 41 L.Ed. 624 (1897) ("The law presumes that every man intends the legitimate consequences of his own acts."). From this definition and usage, the plain meaning of "intend" does not indicate that intent must be proven by any particular kind of evidence. In addition, the text of the structure-or-function and the treatment-of-disease definitions does not limit the type of evidence upon which FDA may rely to establish intended use. Indeed, Plaintiffs have made no attempt to argue that the text of the FDCA supports their position that only manufacturer representations can establish intended use. It is clear that the plain language of the structure-or-function definition does not prohibit consideration of evidence other than manufacturer representations in determining a product's intended use. Since, however, the text does not disclose the types of evidence upon which FDA may rely to establish intended use, it is necessary to examine the relevant legislative history.

Plaintiffs assert that the legislative history of the phrases "intended to affect" and "intended for use" is unambiguous and, furthermore, supports their argument that intended use must be established by manufacturer representations. (Pls.' Second Br. Supp. Mot. Summ. J. at 8.) First, Plaintiffs note the following section of a Senate Report which addresses the method of determining whether a product would, for example, meet the Act's "food" or "drug" definitions:

> The use to which the product is to be put will determine the category into which it will fall. . . . The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put.

S. Rep. No. 74-361, at 4 (1935); *see also* S. Rep. No. 73-493, at 111-12 (1934) (same). This statement is not unambiguous, and, moreover, does not clearly support Plaintiffs' position. The first sentence is consistent with FDA's position that the use of the product can establish intended use. In addition, the second sentence does not reveal that Congress intended to limit the types of evidence that could be relied on to establish intended use. Indeed, Congress' use of "can" rather than "will" arguably shows that Congress did not intend for manufacturer representations to provide the only evidence of intended use.

Second, Plaintiffs cite to testimony of FDA Chief Campbell in which he explained that an ordinary product, such as a lamp, would be subject to FDA's jurisdiction if, for example, it were marketed as a cure for blindness. Testimony on S. 2800, 73d Cong., at 518

(1934). Plaintiffs conclude that this legislative history clearly reveals that both Congress and FDA understood that FDA's jurisdiction "was limited to products *represented* to provide medical or other health benefits." (Pls.' Second Br. Supp. Mot. Summ. J. at 9.) As mentioned above regarding the first issue, the court should be and is unable to conclude from the testimony of one FDA representative to a congressional committee that Congress expressly incorporated that person's understanding of the bill into the final legislation. In any event, these two pieces of legislative history are not "unambiguous" and, moreover, do not clearly show that Congress intended FDA to rely exclusively upon evidence of manufacturer representations to establish intended use.

Plaintiffs find support for their interpretation of "intended use" in prior judicial construction of the phrase and reason that courts have construed the FDCA to require evidence of manufacturer representations to establish intended use. Although it is true that no court has ever found that a product is "intended for use" or "intended to affect" within the meaning of the FDCA absent manufacturer claims as to that product's use, no court has held that intended use can be established solely by promotional representations. Furthermore, courts have acknowledged, albeit *in dicta*, that FDA may rely on other types of evidence to establish intended use. *United States v. Article of 216 Cartoned Bottles, "Sudden Change,"* 409 F.2d 734, 739 (2d Cir. 1969) ("It is well settled that the intended use of a product may be determined from its label, accompanying labeling, promotional material, advertising and any other relevant source."); *ASH v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980) (In the absence of promotional

claims, FDA would need to make a substantial showing of evidence of consumer use to justify an inference as to vendor intent.); *National Nutritional Foods Ass'n v. FDA*, 504 F.2d 761, 789 (2d Cir.1974) (In considering whether high potency vitamins sold without therapeutic representations are drugs, FDA is "free to pierce . . . a manufacturer's . . . misleadingly 'nutritional' labels to find actual therapeutic intent on the basis of objective evidence."); *United States v. 250 Jars U.S. Fancy Pure Honey*, 218 F.Supp. 208, 211 (E.D. Mich. 1963) (To find intended use, a "court is not limited to the labels on such article or to the labeling which accompanies it, but may look at all relevant sources."), *aff'd*, 344 F.2d 288 (6th Cir. 1965); *United States v. Ten Cartons Ener-B Vitamin B-12*, 72 F.3d 285, 287 (2d Cir.1995) (An article can be a drug under 21 U.S.C. § 321(g)(1)(C) for reasons other than claims made in the label or labeling, such as "method of intake."). Certainly, courts have recognized that evidence other than manufacturer claims could be used to establish intended use within the meaning of § 321(h)(3).

Finally, Plaintiffs argue that FDA's own regulations require evidence of manufacturer representations to establish intended use. *See* 21 C.F.R. §§ 201.128, 801.4 (defining "intended use" regarding drugs and devices, respectively).[15] Although the regulations defining "in-

[15] 21 C.F.R. §§ 201.128 and 801.4 provide, in relevant part, that:

> The words "intended uses" or words of similar import ... refer to the objective intent of the persons legally responsible for the labeling of drugs. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.

tended use" clearly anticipate the establishment of intended use through evidence of promotional claims, the plain language does not prohibit the establishment of intended use by other evidence. To illustrate, the regulations specifically provide that intent may be shown by circumstances surrounding the sale of the article and that one such circumstance could be the offering and use of a product for a purpose for which it is neither advertised nor labeled with the manufacturer's knowledge. The regulations defining "intended use" do not prohibit reliance on evidence other than manufacturer representations to establish intended use.

The plain language and the legislative history of the drug and device definitions do not reveal that Congress clearly intended for FDA to rely only upon evidence of manufacturer representations to establish intended use. In addition, past judicial and agency construction of the definitions does not foreclose consideration by FDA of

other evidence to establish intended use. Even so, the court must still determine whether FDA properly relied upon evidence of foreseeability, actual consumer use, and internal manufacturer memoranda to establish intended use.

i. Foreseeable Use.

Although the text of the "drug" and "device" definitions does not expressly state that FDA may consider evidence of foreseeability to establish intended use, nothing in the text or the legislative history of the FDCA prohibits consideration of such evidence. Thus, Congress has not expressed a clear intent regarding whether FDA may consider evidence of foreseeability to establish intended use within the meaning of the FDCA and, finding FDA's interpretation to be reasonable, this court will defer to it. *See Chevron*, 467 U.S. at 845, 104 S. Ct. at 2783 ("Once [the court] determine[s], after its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], the question before it [is] . . . whether the [agency's] view . . . is a reasonable one.").

ii. Actual Consumer Use.

Plaintiffs assert that FDA may not rely on evidence of actual use to establish intended use within the meaning of the FDCA. Nothing in the text or legislative history of the FDCA prohibits consideration of actual use to establish intended use. Indeed, one House Report expressly contemplates reliance upon such evidence. See H.R.Rep. No. 94-853, at 14 (1976) (FDA may consider "actual use of a product in determining whether or not it is a device."); *see also United States v.*

22 Devices "The Ster-O-Lizer MD-200", 714 F. Supp. 1159, 1165 (D. Utah 1989) (Objective intent may be shown "not only by a product's labeling claims, advertising or written statements relating to the circumstances of a product's distribution, but also by a product's actual use.") (internal citations omitted). Moreover, although no court has expressly held that intended use may be established by evidence of actual use, no court has ever prohibited reliance on such evidence. Some courts have even noted *in dicta* that evidence of consumer use may establish intended use within the meaning of the FDCA. *See ASH v. Harris*, 655 F.2d 236, 240 (D.C. Cir. 1980) (If consumers "use the product predominantly—and in fact nearly exclusively—with the appropriate intent . . .[,] the requisite statutory intent can be inferred."); *National Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688, 703 (2d Cir. 1975) (intended use under the treatment-of-disease definition could possibly be inferred from evidence of near exclusive consumer use). Other courts have also noted in dicta that evidence of manufacturer intent can be corroborated by evidence of consumer use. *See United States v. Kasz Enterprises, Inc.*, 855 F. Supp. 534, 539 (D. R.I. 1994) (Intended use "can be demonstrated by . . . evidence that the vendor is aware that his product is being offered or used by others for a purpose for which it is neither labeled nor advertised."), *modified on other grounds*, 862 F. Supp. 717 (D.R.I.1994); *United States v. 789 Cases Latex Surgeons' Gloves*, 799 F. Supp. 1275, 1285, 1294-95 (D. P.R. 1992) (intended use determined by all the facts, including "actual use"); *United States v. Two Plastic Drums*, 761 F. Supp. 70, 72 (C.D. Ill. 1991) ("[A] court should examine a wide range of evidence, including . . . actual use of the product."), *aff'd*, 984 F.2d 814 (7th

Cir.1993). Still other courts have expressly relied on actual use as a factor contributing to the establishment of intended use. *See United States v. An Article of Device Toftness Radiation Detector*, 731 F.2d 1253, 1257 (7th Cir. 1984) (intended use established in part by witness testimony that device had been used to treat patients); *United States v. 22 Devices "The Ster-O-Lizer MD-200"*, 714 F. Supp. at 1165 (court noted that the product was used in the surgical treatment of patients); *United States v. Device Labeled "Cameron Spitler Amblyo-Syntonizer"*, 261 F. Supp. 243, 245 (D. Neb. 1966) (although claimant contended that no representations had been made about the product, he admitted the use of the product).

Again, the FDCA does not reveal that Congress clearly intended to permit or prohibit reliance on evidence of actual use to establish intended use. Finding FDA's determination that it may consider evidence of actual use to establish intended use to be reasonable, especially in light of judicial recognition of the possibility, the court will defer to FDA's interpretation. *See Chevron*, 467 U.S. at 845, 104 S. Ct. at 2783 ("Once [the court] determine [s], after its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], the question before it [is] . . . whether the [agency's] view . . . is a reasonable one.").

iii. Statements, Knowledge, and Action of Manufacturers.

Plaintiffs assert that FDA may not establish intended use based on evidence of the subjective intent of manufacturers. As previously discussed in the sections

regarding evidence of foreseeability and actual use, neither the text nor the legislative history of the FDCA reveals Congress' clear intent to prohibit consideration of such evidence. The court agrees, however, that FDA's own regulations defining "intended use" provide that intended use may be established only by evidence of objective intent. *See* 21 C.F.R. §§ 201.128, 801.4 ("The words 'intended uses' or words of similar import . . . refer to the objective intent of the persons legally responsible for the labeling of drugs."). Nonetheless, since FDA found that each of the three types of evidence upon which it relied provided independent bases for finding intended use within the meaning of the Act, 61 Fed. Reg. at 44,632-33, the court concludes that FDA adequately and properly supported its finding of intended use with evidence of foreseeability and consumer use.

b. Tobacco Products Affect the Structure or Function of the Body Within the Meaning of the Federal Food, Drug, and Cosmetic Act.

Plaintiffs infer that Congress intended for the structure-or-function definition of device to "apply only to products that are marketed to provide some medical or other health benefit to users." (Pls.' Second Br. Supp. Mot. Summ. J. at 5.) They support their argument in part by noting that Congress entitled its 1976 amendments to the FDCA's device provisions the "Medical Device Amendments" ("MDA"). The definition of device, however, expressly includes those products "intended to affect the structure or any function of the body of man or other animals" and gives no indication that it is to apply only to those devices with a medical purpose. 21 U.S.C. § 321(h). The plain language of the

structure-or-function definition of "device" does not limit the statute's reach to only those devices with a medical purpose.

Neither does the legislative history indicate that Congress intended to limit the scope of the structure-or-function definition to apply only to devices with a medical purpose. Congress included the structure-or-function definition in the FDCA in 1938. Nothing in the legislative history of the 1938 Act specifically addresses the meaning of the phrase "intended to affect the structure or any function of the body." Congress did explain that the FDCA was intended to broaden the scope of the older food and drug laws to reach, among other things, "therapeutic devices." *See* H.R.Rep. 75-2139, at 2 (1938). The legislative history of the MDA also reveals some discussion of the general purpose of the device provisions. For example, the Senate Report accompanying the MDA states that "[i]ncreasing numbers of patients have been exposed to increasingly complex devices which pose serious risk if inadequately tested or improperly designed or used" and that FDA lacked the tools under the FDCA to adequately regulate such devices. S.Rep. No. 94-33 (1976) U.S. Code Cong. & Admin. News 1976 p. 1070. It also notes that Congress recognized the need for "regulation to assure that the public is protected and that health professionals can have more confidence in the performance of devices." *Id.* The Report further states that the medical device legislation was "intended to assure that medical devices . . . meet the requirements of safety and effectiveness before they are put in widespread use throughout the United States." *Id.*

Consequently, the legislative history of the structure-or-function definition of "device" suggests that Congress was concerned about the lack of regulation of devices that posed a danger to the public. Although Congress clearly intended that the FDCA apply to devices used within the medical community, nothing in the legislative history indicates that Congress intended to limit the FDCA's reach to devices offered for beneficial or therapeutic purposes. The fact that Congress contemplated the Act's application to certain medical devices does not foreclose application of the Act to other devices, especially where the text does not preclude such application.

Finally, Plaintiffs urge the court to narrowly construe the structure-or-function definition of device, claiming that acceptance of FDA's regulation of non-therapeutic devices could result in FDA regulating almost anything that can be said to affect the structure or function of the body. This argument lacks merit. *See United States v. Sullivan*, 332 U.S. 689, 694, 68 S. Ct. 331, 335, 92 L.Ed. 297 (1948) ("The scope of the [statute] . . . is not to be judicially narrowed . . . by envisioning extreme possible applications. . . . There will be opportunity enough to consider such contingencies should they ever arise.").

The four corners of the text and the legislative history of the structure-or-function definition of device do not reveal the clear intent of Congress to include only medical or therapeutic devices within the jurisdiction of the FDCA. FDA's application of the FDCA to non-therapeutic devices is reasonable and entitled to deference from the court. *See Chevron*, 467 U.S. at 845, 104 S. Ct. at 2783 ("Once [the court] determine[s], after

its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], the question before it [is] . . . whether the [agency's] view . . . is a reasonable one.").

2. The Food and Drug Administration May Regulate Tobacco Products as Medical Devices Pursuant to its Device Authorities.

FDA determined that tobacco products are combination products consisting of the drug nicotine and device components which are intended to deliver nicotine to the body. FDA elected to regulate tobacco products pursuant to its device authorities. Plaintiffs argue that FDA has both contorted and evaded the FDCA and that FDA's application of the Act confirms Plaintiffs' assertion that the FDCA's device provisions "simply do not fit tobacco products." (Pls.' Second Br. Supp. Mot. Summ. J. at 47.) The court must first determine whether tobacco products are combination products within the meaning of the FDCA and then ascertain whether FDA has applied the Act to tobacco products in a permissible manner.

a. Tobacco Products are Combination Products Within the Meaning of the Federal Food, Drug, and Cosmetic Act.

Plaintiffs assert that tobacco products are not combination products within the meaning of the Act for three reasons. First, Plaintiffs urge that "a combination product must consist of two products, each of which could be *separately* regulated" and that tobacco products do not meet that definition. (Pls.' Second Br. Supp. Mot. Summ. J. at 29.) FDA responds that a

combination product consists of a combination of a drug, device, and/or biological product, and that the total product need only contain components that meet two of those definitions.

The FDCA does not separately define "combination product," stating only that a combination product is a product "that constitute[s] a combination of a drug, device, or biological product." 21 U.S.C. § 353(g)(1). The plain language of the definition, therefore, does not reveal whether it was Congress' intention that each component be subjected separately to regulation.[16]

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[16] FDA's regulations define "combination product" to include:

(1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(2) Two or more separate products packaged together in a single package or as a unit and comprised of drugs and device products, device and biological products, or biological and drug products;

(3) A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or

(4) Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Since Congress has not expressed its intent regarding whether combination products must be comprised of two separately regulable products, and since FDA's interpretation is reasonable, the court should and will uphold that interpretation. *See Chevron*, 467 U.S. at 845, 104 S. Ct. at 2783 ("Once [the court] determine[s], after its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], the question before it [is] . . . whether the [agency's] view . . . is a reasonable one.").

Second, Plaintiffs contend that the device component of tobacco products does not meet the definition of "device" because it does not itself affect the structure or function of the body. FDA responds that the device component need only have an indirect effect on the structure or function of the body to meet the definition of "device." The plain language of the structure-or-function definition does not preclude FDA's interpretation. Additionally, FDA has regulated as devices products that do not themselves directly affect the structure or function of the body, but instead deliver to the body an agent or substance that has such a direct effect. *See, e.g.*, 21 C.F.R. § 878.4635 (ultraviolet lamps

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(f) Device has the meaning given the term in [21 U.S.C. § 321(h)].

(g) Drug has the meaning given the term in [21 U.S.C. § 321(g)].

21 C.F.R. § 3.2.

FDA avows that it routinely regards the following products as combination products: pre-filled delivery systems, such as pre-filled syringes, intravenous infusion pumps, nebulizers, metered dose inhalers, and nicotine patches. 61 Fed. Reg. at 45,211.

that deliver ultraviolet light which causes tanning); 21 C.F.R. § 878.4800 (surgical stapler that delivers staples that affect body tissues by holding them together); 21 C.F.R. § 880.5475 (jet lavage that delivers sterile fluid that cleans wounds); 21 C.F.R. § 880.5570 (hypodermic needle that delivers drug substance to site on body); 21 C.F.R. § 868.5580 (oxygen mask that delivers oxygen for absorption by the lungs).

Nothing in the text nor the history of the FDCA suggests that a product must directly, rather than indirectly, affect the structure or function of the body to be subject to regulation under the Act. Furthermore, FDA's interpretation is reasonable. *See Chevron*, 467 U.S. at 845, 104 S. Ct. at 2783 ("Once [the court] determine[s], after its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], the question before it [is] . . . whether the [agency's] view . . . is a reasonable one.").

Third, Plaintiffs protest that tobacco products have no device components within the meaning of the Act because they fall within an explicit exception of the device definition. The FDCA excludes from the definition of "device" a product "which . . . achieve[s] its primary intended purposes through chemical action within or on the body of man or other animals and which is . . . dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h)(3). FDA has found that the primary mode of action of tobacco products is that of a drug. 61 Fed. Reg. at 44,400-03, 45,209-18. Plaintiffs conclude that, under FDA's own analysis, tobacco products achieve their primary intended purposes through chemical action within or on the body of man and

depend upon being metabolized for the achievement of their primary intended purposes.

FDA responds that it found tobacco products to be combination products and that, although a device or device component cannot achieve its primary purpose by chemical action within or on the body under the Act, a combination product consisting of a drug and a device may. FDA further contends that the device component of tobacco products does not rely on chemical actions within or on the body to achieve its primary function and thereby is not excluded from the device definition. FDA has found that the device component of cigarettes consists of the tobacco blend, filter, and cigarette ventilation system, and that the device component of smokeless tobacco consists of the processed tobacco, and, in some products, the pouch. FDA states that the primary function of the device component of cigarettes is to "release a nicotine-containing aerosol, i.e., the tobacco smoke, that, upon combustion outside the body, is inhaled by the smoker and serves as a vehicle for nicotine delivery." 61 Fed.Reg. at 45,209. FDA claims that the primary function of the device component of smokeless tobacco is to "deliver the nicotine to the cheek and gum tissue for absorption," 61 Fed.Reg. at 45,213, and, where the porous pouch is used, to "hold[ ] the processed tobacco in position in the mouth, controlling the absorption of nicotine into the buccal mucosa." 61 Fed.Reg. at 45,214.

The court finds that the device components of tobacco products fully satisfy the device definition even though the drug component achieves its primary intended purpose through a series of chemical actions inside the body.

b. The Food and Drug Administration May Regulate Tobacco Products Pursuant to its Device Authorities.

Upon determination that tobacco products' primary mode of action is that of a drug, FDA, in accordance with 21 U.S.C. § 353(g),[17] assigned to the agency's Center for Drug Evaluation and Research ("CDER") the responsibility of premarket review. FDA also directed CDER to apply the Act's device provisions because FDA thought that regulation of tobacco products as devices "is the available option that is the most consistent with both the [A]ct and the agency's mission to protect the public health." 61 Fed.Reg. at 44,398.

Plaintiffs contend that once FDA determined that the primary mode of action of tobacco products is that

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[17] 21 U.S.C. § 353(g) provides, in relevant part, that:

(g) Combinations of drugs, devices, or biological products

(1) The Secretary shall designate a component of the [FDA] to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

(A) a drug (other than a biological product), the persons charged with premarket review of drugs shall have primary jurisdiction,

(B) a device, the persons charged with premarket review of devices shall have primary jurisdiction,

. . . .

(2) Nothing in this subsection shall prevent the Secretary from using any agency resources of the [FDA] necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.

of a drug, FDA lacked discretion to regulate them pursuant to its device, rather than its drug, authorities. As Plaintiffs note, the distinction between "drug" and "device" has legal and practical significance because different regulatory schemes apply to each. Plaintiffs assert that, just as FDA lacks discretion to regulate what it deems to be a "drug" pursuant to its device authorities or to regulate what it deems to be a "device" pursuant to its drug authorities,[18] it lacks discretion to choose which authorities to apply to combination

[18] In the Medical Device Amendments of 1976 ("MDA"), Congress amended the "device" definition to provide that a device "does not achieve its primary intended purposes through chemical action within or on the body of man . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes." The reports accompanying the MDA suggest that Congress amended the definition to draw a clearer line between the "drug" and "device" definitions at least in part in response to the Supreme Court's decision in *United States v. An Article of Drug Bacto-Unidisk*, 394 U.S. 784, 89 S. Ct. 1410, 22 L.Ed.2d 726 (1969). *See* H.R.Rep. No. 94-853 (1976); S. Rep. No. 94-33 (1975). *Bacto-Unidisk* involved a challenge to FDA's decision to regulate a product as a drug, rather than as a device. FDA wanted to subject the product to premarket review, but, at that time, lacked authority to subject a device to premarket review. Thus, FDA tried to regulate the product as a drug. The Supreme Court upheld FDA's actions, noting that the statute was of little assistance in determining precisely what differentiated a "drug" from a "device." The House and Senate Reports indicate that Congress amended the "device" definition to clarify the distinction between "drugs" and "devices" and to assist FDA in avoiding entanglement in legal battles. *Id.* Although Plaintiffs interpret the legislative history of the MDA as indicating that Congress intended to limit FDA's discretion to choose regulatory authorities, the court interprets the legislative history as primarily revealing Congress' concern that FDA's device authority was deficient and its intent to enhance those authorities. *Id.*

products. Although it is clear to the court that FDA may not regulate as a "device" a product that meets only the definition of "drug," the question remains how FDA is to regulate a product that contains both drug and device components and thereby meets the definition of a combination product under the Act.

Section 353(g), the only provision of the FDCA relevant to the regulation of combination products, provides that FDA must determine the primary mode of action of a combination product, and that FDA's determination directs the regulatory path by which FDA conducts premarket review of the product. FDA contends that a product need not be regulated pursuant to FDA's drug authorities merely because the CDER has primary jurisdiction for premarket review of the product.

FDA's interpretation of § 353(g) is not prohibited by the plain language of the section. The section merely provides that, for example, the persons charged with premarket review of drugs shall have primary jurisdiction over combination products whose primary mode of action is that of a drug. Thus, the text of § 353(g) does not reveal whether Congress intended for FDA to have discretion to regulate a combination product pursuant to the authority of its choice.

The legislative history of § 353(g) provides little guidance regarding Congress' intent. Congress included the combination product provision in the Safe Medical Devices Act ("SMDA") of 1990. The Senate Report states that:

The Committee is aware of the difficulty under the present law in determining the jurisdictional basis for regulating products that are comprised of combinations of drugs, devices, or biologics. This provision will provide the Secretary with firm ground rules to direct products promptly to that part of the FDA responsible for reviewing the article that provides the primary mode of action of the combination product. Various persons from industry have expressed the view that a weakness in FDA's premarket review process is the determination of how to regulate combination products. This provision should assist the Secretary in avoiding delays in making that determination, and is important since more combination products are coming before the agency for premarket review

. . . .

S. Rep. No. 101-513, 101st Cong., 2nd Sess. (1990). The House Conference Report refers to § 353(g) as describing the "general procedures for determining the appropriate component of the FDA to review premarket submissions for products that are comprised of any combination of drugs, devices, or biologicals." H.R. Conf. Rep. No. 101-959, at 29 (1990). The court does not find in this legislative history the clear intent of Congress that FDA apply its drug authorities to combination products whose primary mode of action is that of a drug and its device authorities to combination products whose primary mode of action is that of a device.

The court finds that Congress has not expressed any intent as to whether FDA has discretion to apply the regulatory authority of its choice to combination products. The court acknowledges that FDA may not apply the regulatory authority of its choice to non-combination products. On the other hand, the court notes that Congress may have intended for FDA, with its expertise, to apply what it deemed to be the most appropriate regulatory authority to different combination products.[19] In any event, absent any guidance from Congress, the court is constrained by the principles of statutory construction set forth in *Chevron*. Thus, although the court hesitates to agree with FDA that the agency has unfettered discretion to apply the regulatory authority of its choice to combination products, the court finds that the intent of Congress is not clear and, finding FDA's interpretation to be at least reasonable, defers to FDA's interpretation. *See Chevron*, 467 U.S. at 845, 104 S. Ct. at 2783 ("Once [the court] determine[s], after its own examination of the legislation, that Congress did not actually have an intent regarding [the issue], the question before it [is] . . .

[19] FDA notes that, shortly following passage of the Safe Medical Devices Act ("SMDA") in 1990, it adopted implementing regulations and delegations of authority which reflect its contemporaneous interpretation of the SMDA as authorizing it to apply the most appropriate regulatory authorities to any given combination product. See 61 Fed.Reg. at 44,402-03. In addition, FDA notes that it has previously exercised discretion to apply what it considered to be the most appropriate regulatory authority to a combination product when it regulated the intravenous infusion pump as a device. An intravenous infusion pump is a drug delivery device which consists of a device (the pump) and a drug (the diluent) and which is designed to be sold prefilled. FDA states that it exercised its discretion to regulate intravenous pumps as devices because whereas the agency was familiar with the drug component of the product, it was not familiar with the device component which was new and raised significant regulatory questions. *See* 61 Fed.Reg. at 44,403.

whether the [agency's] view . . . is a reasonable one.").

3. Portions of the Food and Drug Administration's Restrictions are Not Authorized Under the Federal Food, Drug, and Cosmetic Act's Device Authorities.

The court has found that FDA properly regulated tobacco products pursuant to its device authorities. The question remains whether FDA has properly applied its device authorities to tobacco products. The Regulations' requirements fall into essentially three categories: restrictions on advertising and promotion,[20] restrictions on access,[21] and labeling requirements.[22] FDA promulgated the first two categories of restrictions pursuant to 21 U.S.C. § 360j(e), and the last pursuant to 21 U.S.C. § 352. The court will address each category of restrictions in turn.

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[20] The promotional and advertising restrictions limit certain advertising to a black-and-white text-only format, restrict the trade or brand name of certain tobacco products, prohibit the sale or distribution of brand-identified promotional non-tobacco items such as hats and tee shirts, and prohibit use of a brand name of a tobacco product to sponsor entries, teams, sporting and other events.

[21] The access restrictions prohibit the sale of tobacco products to individuals under the age of 18, require retailers to verify a purchaser's age by photographic identification, prohibit the sale of tobacco products through vending machines and self-service displays except in facilities where individuals under the age of 18 are not permitted, prohibit distribution of free samples, and prohibit the sale of cigarette packages containing fewer than 20 cigarettes.

[22] FDA requires tobacco product packages, cartons, and boxes to bear the established name of the product and a statement of intended use.

a. Section 360j(e) Does Not Authorize Restrictions on the Promotion and Advertisement of Tobacco Products.

Section 360j(e), entitled "Restricted devices," provides:

> (1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—
>
> (A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or
>
> (B) upon such other conditions as the Secretary may prescribe in such regulation,
>
> if, oecause of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. No condition prescribed under subparagraph (B) may restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device. No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board. A device subject to a regulation under this subsection is a restricted device.
>
> (2) The label of a restricted device shall bear such appropriate statements of the restrictions required

by a regulation under paragraph (1) as the Secretary may in such regulation prescribe.

21 U.S.C. § 360j(e).

FDA determined that tobacco products are restricted devices within the meaning of § 360j(e) because, due to the "unique circumstances surrounding the use of tobacco products, the only way to provide a reasonable assurance of the safety of these products is to prevent children and adolescents from using and becoming addicted to them" and that, "without the restrictions contained in the Regulations, there cannot be a reasonable assurance of the safety and effectiveness of these products." (Defs.' Br. Opp'n Pls.' Mot. Summ. J. at 93.) FDA asserts that since tobacco products are restricted devices, it may restrict their "sale, distribution, or use," pursuant to § 360j(e). FDA further asserts that it may restrict the advertising and promotion of tobacco products, explaining that advertising and promotion constitutes an "offer of sale" and, moreover, that an "offer of sale" is part of the "sale" of a product.

Plaintiffs contend, and the court agrees, that FDA may not restrict advertising and promotion pursuant to § 360j(e). First, both as ordinarily defined[23] and as used

[23] A dictionary defines sale as:

1. The exchange of goods or services for an amount of money or its equivalent; the act of selling. 2. An instance of selling property. 3. An opportunity for selling or being sold; demand. 4. Availability for purchase; *a store where pets are for sale.* 5. A selling of property to the highest bidder; auction. 6. A special disposal of goods at lowered prices; *coats on sale this week.* 7. sales. a. Activities involved in the selling of goods or services. b. Gross receipts.

in the phrase "may . . . be restricted to sale, distribution, or use," the word "sale" does not encompass the advertising or promotion of a product. Second, as Plaintiffs note, although Congress expressly used the words "offer for sale"[24] and "advertising" or "advertisements"[25] elsewhere in the FDCA, it chose not to use such language in § 360j(e).

Even if "sale," as used within § 360j(e), could be construed to encompass the advertising and promotion of a product, the court finds that the section's grant of authority to FDA to impose "other conditions" on the sale, distribution, or use of restricted devices does not authorize FDA to restrict advertising and promotion. The phrase "other conditions" must be construed within the context of § 360j(e) and other relevant sections of the FDCA. Section 360j(e) authorizes FDA to restrict the sale, distribution, or use of certain devices to prescription sale or other conditions necessary to provide a reasonable assurance of safety and effectiveness. The restriction on the advertising and promotion of a product does not fit within this framework. Furthermore, § 360j(e) must be construed in relation to 21 U.S.C. § 353(b),[26] which Plaintiffs assert is the counter-

The American Heritage Dictionary 1085 (2d ed.1991). The only part of the definition that could encompass promotion and advertising is part 7, which defines "sales." Section 360j(e) does not authorize FDA to restrict general "sales" activities.

[24] See 21 U.S.C. §§ 331(m), 331(*o*), and 353(c).

[25] See 21 U.S.C. §§ 321(n), 331(*l*), 331(n), 352(n), 352(q), and 352(r).

[26] Section 353(b) provides:

(1) A drug intended for use by man which—

part to § 360j(e) and which authorizes FDA to constrain certain drugs to prescription status. Section 353(b), like § 360j(e), authorizes FDA to restrict drugs to prescription sale. It is true, as FDA notes, that FDA's authority is broader under § 360j(e) than under § 353(b) because FDA may impose pursuant to the former "other conditions" on the sale, distribution, or use of a restricted device. Nonetheless, the meaning of "other conditions" cannot be considered without context, and the court finds that "other conditions" cannot be so broadly construed as to encompass conditions on advertising and promotion.[27]

(A) is a habit-forming drug to which section 352(d) of this title applies; or

(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(C) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such a drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

[27] The court also notes that the legislative history of the restricted device provision, which was enacted as part of the MDA in 1976, suggests that Congress did not intend to give to FDA the

In addition, the court finds that Congress' delegation to FDA of limited authority to restrict the advertising of devices elsewhere in the FDCA suggests that § 360j(e) should not be construed so as to allow FDA to restrict advertising and promotion. The court notes that just as Congress gave FDA authority to limit drugs to prescription status in § 353(b), but gave FDA authority to regulate prescription drug advertisements

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authority to impose unlimited conditions on the sale of restricted devices. The House Report provides, in relevant part, as follows:

Restricted Devices.—Because of the sophistication and potentially hazardous nature of some medical devices, the proposed legislation authorizes the Secretary to require that the sale or distribution of a device be restricted if he determines that, because of its potentiality for harmful effect or the collateral measures necessary to its use, there cannot otherwise be reasonable assurance of its safety and effectiveness. Under this provision . . ., such a device may be restricted to the extent that it may be sold or distributed only upon the oral or written authorization of a practitioner licensed by law to administer or use the device, or upon such other conditions as the Secretary may prescribe, except that no condition limiting the use of a device to categories of physicians defined by their training or experience may be imposed.

This provision supersedes and adds to existing authority utilized by [FDA] to require that certain devices by [sic] dispensed only upon prescription. . . .

In addition to authorizing the Secretary to limit a device to prescription status, conditions on sale or distribution could include use only within hospitals or clinics. Also, there are categories of health professionals other than physicians that have unique skills appropriate to the use of medical devices such that certain devices which would not be appropriate for use by the ordinary layman could be authorized for use by trained nurses and technicians.

H.R. 94-853 at 24-25 (1976).

in § 352(n), Congress gave FDA authority to limit certain devices to prescription status in § 360j(e), but gave FDA authority to regulate the advertising of such devices in §§ 353(q)[28] and 352(r).[29] Indeed, the fact that Congress has specifically granted to FDA the authority to regulate advertising of restricted devices in a separate section supports the court's finding that Congress did not intend to grant FDA such authority under § 360j(e).[30]

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[28] 21 U.S.C. § 352(q) provides, in relevant part:

> A drug or device shall be deemed to be misbranded—
>
> . . . .
>
> (q) Restricted devices using false or misleading advertising or used in violation of regulations.
>
> In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title.

[29] Section 352(r) requires that advertisements for any restricted device include certain information: the established name of the device; a brief statement of the intended uses of the device and relevant warnings; and, if determined necessary after a hearing, a description of the device's components. Section 352(r) further provides that "no advertisement of a restricted device . . . shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to" the Federal Trade Commission Act. Plaintiffs contend, and the court agrees, that § 352(r) reveals Congress' intention that the Federal Trade Commission have primary jurisdiction over advertising.

[30] The court finds that § 352(q) does not provide independent authority for advertising restrictions, but rather was intended to enable FDA to take action against an advertised product that violated the restrictions validly imposed pursuant to § 360j(e).

Thus, the court finds that § 360j(e) does not grant to FDA the authority to impose restrictions on the advertisement and promotion of tobacco products. The court will, therefore, strike those regulations restricting the advertisement and promotion of tobacco products.[31]

b. Section 360j(e) Authorizes the Food and Drug Administration to Impose Restrictions on Access to Tobacco Products.

The court finds that § 360j(e) can be construed to authorize the access restrictions imposed by FDA. First, the access restrictions imposed by FDA, unlike its advertising and promotion restrictions, directly restrict the sale or distribution of tobacco products within the meaning of § 360j(e). Second, the court finds that such conditions on the sale or distribution of tobacco products fit within what Congress intended for FDA to impose pursuant to its authority to impose "other conditions." Thus, FDA's access restrictions will stand.[32]

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[31] The court does not find, as Plaintiffs urge, that FDA's unlawful imposition of advertising and promotion restrictions pursuant to § 360j(e) evidences that FDA lacks jurisdiction to regulate tobacco products under the FDCA. The court has found that tobacco products fall within the definitions of the FDCA and that FDA may regulate tobacco products pursuant to its device authorities.

[32] Plaintiff National Association of Convenience Stores asserts that the Regulations' ban on self-service displays implicates the First Amendment. The court finds that the requirement that tobacco products be stored behind a counter and sold in a face-to-face exchange between a retailer and a consumer does not implicate the First Amendment. Retailers may still exhibit store

c. Section 352 Authorizes the Food and Drug Administration to Impose Labeling Restrictions on Tobacco Products.

FDA, pursuant to § 352(r), requires tobacco products to have a statement of intended use and the established name printed on the packages. The court finds that § 352(r) clearly authorizes FDA to require restricted devices to bear the product's established name and a statement of intended use.

In conclusion, although FDA has the authority under the FDCA to impose access restrictions and labeling requirements on tobacco products, FDA lacks the authority to restrict their advertising and promotion.

II. CONCLUSION

For the reasons discussed herein, Plaintiffs' Motion for Summary Judgment will be granted in part and denied in part.[33]

An order in accordance with this memorandum opinion shall be filed contemporaneously herewith.

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displays promoting the sale of tobacco products. They simply will be prohibited from storing tobacco products on such displays.

[33] In light of the court's finding that FDA lacks authority under the FDCA to restrict the promotion and advertising of tobacco products, the court declines to determine whether the promotion and advertising restrictions violate the First Amendment.

ORDER

For the reasons set forth in the memorandum opinion entered contemporaneously herewith,

IT IS THEREFORE ORDERED AND ADJUDGED that Plaintiffs' Motion for Summary Judgment is granted as to the Regulations' restrictions on the promotion and advertising of tobacco products.

IT IS FURTHER ORDER AND ADJUDGED that Plaintiffs' Motion for Summary Judgment is denied as to the Regulations' access restrictions and labeling requirements.

This order involves controlling questions of law as to which there is substantial ground for difference of opinion. Furthermore, an immediate appeal from this order may materially advance the ultimate termination of the litigation. Therefore, the court certifies this order for an interlocutory appeal pursuant to 28 U.S.C. § 1292(b).

IT IS FURTHER ORDERED that the Regulations heretofore implemented prohibiting the sale of tobacco products to minors shall remain in full force and effect pending appeal by Plaintiffs.

IT IS FURTHER ORDERED that the Food and Drug Administration shall not implement any of the additional Regulations set for implementation on August 28, 1997, pending further orders by the court.

IT IS FURTHER ORDERED that nothing set forth in this order concerning the time of implementation of the

Regulations shall prohibit either side from presenting motions to the court for a reconsideration as to the implementation of the Regulations pending appeal.

IT IS FURTHER ORDERED that absent a timely appeal or absent permission of the Court of Appeals for the Fourth Circuit to proceed with an interlocutory appeal, this matter shall proceed for ultimate disposition by the court.

APPENDIX C

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 97-1604

BROWN & WILLIAMSON TOBACCO CORPORATION; LORILLARD TOBACCO COMPANY; PHILIP MORRIS, INCORPORATED; RJ REYNOLDS TOBACCO COMPANY, PLAINTIFFS-APPELLANTS

AND

COYNE BEAHM, INCORPORATED; LIGGETT GROUP, INCORPORATED, PLAINTIFFS

v.

FOOD & DRUG ADMINISTRATION; DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD AND DRUGS, DEFENDANTS-APPELLEES

ATTORNEYS GENERAL OF THE STATE OF MINNESOTA; STATE OF ALASKA; STATE OF ARIZONA; STATE OF ARKANSAS; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF FLORIDA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF KANSAS; STATE OF MAINE; STATE OF MARYLAND; STATE OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MISSISSIPPI; STATE OF MISSOURI; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK;

STATE OF NORTH DAKOTA; STATE OF OHIO;
STATE OF OKLAHOMA; STATE OF OREGON;
STATE OF PENNSYLVANIA; STATE OF RHODE ISLAND;
STATE OF SOUTH DAKOTA; STATE OF TEXAS;
STATE OF UTAH; STATE OF VERMONT;
STATE OF WASHINGTON; STATE OF WEST VIRGINIA;
STATE OF WISCONSIN; THE CITY AND COUNTY OF
SAN FRANCISCO; PUBLIC CITIZEN; THE AMERICAN
ACADEMY OF PEDIATRICS; AMERICAN CANCER
SOCIETY; AMERICAN COLLEGE OF PREVENTIVE
MEDICINE; AMERICAN HEART ASSOCIATION;
AMERICAN LUNG ASSOCIATION; AMERICAN MEDICAL
ASSOCIATION; AMERICAN MEDICAL WOMEN'S
ASSOCIATION; AMERICAN PUBLIC HEALTH
ASSOCIATION; AMERICAN SOCIETY OF ADDICTION
MEDICINE; THE HMO GROUP; NATIONAL ASSOCIATION
OF ELEMENTARY SCHOOL PRINCIPALS; NATIONAL
ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS;
NATIONAL CENTER FOR TOBACCO-FREE KIDS; STATE
OF KENTUCKY; WASHINGTON LEGAL FOUNDATION
("WLF"); MARIO ANDRETTI; DON GARLITS; AL UNSER;
RUSTY WALLACE; CALE YARBOROUGH; RICHARD
BURR, CASS BALLENGER, HOWARD COBLE, UNITED
STATES REPRESENTATIVES, LAUCH FAIRCLOTH,
UNITED STATES SENATOR, AMICI CURIAE

No. 97-1581

COYNE BEAHM, INCORPORATED; BROWN &
WILLIAMSON TOBACCO CORPORATION; PHILIP MORRIS,
INCORPORATED; RJ REYNOLDS TOBACCO COMPANY;
NATIONAL ASSOCIATION OF CONVENIENCE STORES;

ACME RETAIL, INCORPORATED; UNITED STATES
TOBACCO COMPANY; CONWOOD COMPANY, LP;
NATIONAL TOBACCO COMPANY, LP; PINKERTON
TOBACCO COMPANY; SWISHER INTERNATIONAL,
INCORPORATED; CENTRAL CAROLINA GROCERS,
INCORPORATED; J.T. DAVENPORT, INCORPORATED;
NORTH CAROLINA TOBACCO DISTRIBUTORS
COMMITTEE, INCORPORATED; THE AMERICAN
ADVERTISING FEDERATION; AMERICAN ASSOCIATION
OF ADVERTISING AGENCIES; ASSOCIATION OF
NATIONAL ADVERTISERS, INCORPORATED;
MAGAZINE PUBLISHERS OF AMERICA; THE OUTDOOR
ADVERTISING ASSOCIATION OF AMERICA,
INCORPORATED; POINT OF PURCHASE ADVERTISING
INSTITUTE; LORILLARD TOBACCO COMPANY,
PLAINTIFFS-APPELLEES

AND

LIGGETT GROUP, INCORPORATED, PLAINTIFF

v.

FOOD & DRUG ADMINISTRATION; DAVID A.
KESSLER, M.D., COMMISSIONER OF FOOD AND
DRUGS, DEFENDANTS-APPELLANTS

ATTORNEYS GENERAL OF THE STATE OF MINNESOTA;
STATE OF ALASKA; STATE OF ARIZONA;
STATE OF ARKANSAS; STATE OF COLORADO;
STATE OF CONNECTICUT; STATE OF FLORIDA;
STATE OF HAWAII; STATE OF ILLINOIS;
STATE OF INDIANA; STATE OF IOWA;
STATE OF LOUISIANA; STATE OF KANSAS;
STATE OF MAINE; STATE OF MARYLAND;
STATE OF MASSACHUSETTS; STATE OF MICHIGAN;
STATE OF MISSISSIPPI; STATE OF MISSOURI;
STATE OF MONTANA; STATE OF NEVADA;
STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY;
STATE OF NEW MEXICO; STATE OF NEW YORK;

STATE OF NORTH DAKOTA; STATE OF OHIO;
STATE OF OKLAHOMA; STATE OF OREGON;
STATE OF PENNSYLVANIA; STATE OF RHODE ISLAND;
STATE OF SOUTH DAKOTA; STATE OF TEXAS;
STATE OF UTAH; STATE OF VERMONT;
STATE OF WASHINGTON; STATE OF WEST VIRGINIA;
STATE OF WISCONSIN; CITY AND COUNTY OF
SAN FRANCISCO; PUBLIC CITIZEN; THE AMERICAN
ACADEMY OF PEDIATRICS; AMERICAN CANCER
SOCIETY; AMERICAN COLLEGE OF PREVENTIVE
MEDICINE; AMERICAN HEART ASSOCIATION;
AMERICAN LUNG ASSOCIATION; AMERICAN MEDICAL
ASSOCIATION; AMERICAN MEDICAL WOMEN'S
ASSOCIATION; AMERICAN PUBLIC HEALTH
ASSOCIATION; AMERICAN SOCIETY OF ADDICTION
MEDICINE; THE HMOGROUP; NATIONAL ASSOCIATION
OF ELEMENTARY SCHOOL PRINCIPALS; NATIONAL
ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS;
NATIONAL CENTER FOR TOBACCO-FREE KIDS;
STATE OF KENTUCKY; WASHINGTON LEGAL
FOUNDATION ("WLF"); MARIO ANDRETTI;
DON GARLITS; AL UNSER; RUSTY WALLACE;
CALE YARBOROUGH; RICHARD BURR,
CASS BALLENGER, HOWARD COBLE, UNITED STATES
REPRESENTATIVES, LAUCH FAIRCLOTH, UNITED
STATES SENATOR, AMICI CURIAE

No. 97-1606

COYNE BEAHM, INCORPORATED; BROWN &
WILLIAMSON TOBACCO CORPORATION; LORILLARD
TOBACCO COMPANY; PHILIP MORRIS,
INCORPORATED; RJ REYNOLDS TOBACCO COMPANY;
UNITED STATES TOBACCO COMPANY;
CONWOOD COMPANY, LP; NATIONAL TOBACCO
COMPANY, LP; PINKERTON TOBACCO COMPANY;

SWISHER INTERNATIONAL, INCORPORATED; CENTRAL
CAROLINA GROCERS, INCORPORATED;
J.T. DAVENPORT, INCORPORATED; NORTH CAROLINA
TOBACCO DISTRIBUTORS COMMITTEE, INCORPORATED;
THE AMERICAN ADVERTISING FEDERATION;
AMERICAN ASSOCIATION OF ADVERTISING AGENCIES;
ASSOCIATION OF NATIONAL ADVERTISERS,
INCORPORATED; MAGAZINE PUBLISHERS OF AMERICA;
THE OUTDOOR ADVERTISING ASSOCIATION OF
AMERICA, INCORPORATED; POINT OF PURCHASE
ADVERTISING INSTITUTE; NATIONAL ASSOCIATION OF
CONVENIENCE STORES; ACME RETAIL,
INCORPORATED, PLAINTIFFS-APPELLEES

AND

LIGGETT GROUP, INCORPORATED, PLAINTIFF

v.

FOOD & DRUG ADMINISTRATION; DAVID A.
KESSLER, M.D., COMMISSIONER OF FOOD AND
DRUGS, DEFENDANTS-APPELLANTS.
ATTORNEYS GENERAL OF THE STATE OF MINNESOTA;
STATE OF ALASKA; STATE OF ARIZONA;
STATE OF ARKANSAS; STATE OF COLORADO;
STATE OF CONNECTICUT; STATE OF FLORIDA;
STATE OF HAWAII; STATE OF ILLINOIS;
STATE OF INDIANA; STATE OF IOWA;
STATE OF LOUISIANA; STATE OF KANSAS;
STATE OF MAINE; STATE OF MARYLAND;
STATE OF MASSACHUSETTS; STATE OF MICHIGAN;
STATE OF MISSISSIPPI; STATE OF MISSOURI;
STATE OF MONTANA; STATE OF NEVADA;
STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY;
STATE OF NEW MEXICO; STATE OF NEW YORK;
STATE OF NORTH DAKOTA; STATE OF OHIO;
STATE OF OKLAHOMA; STATE OF OREGON;
STATE OF PENNSYLVANIA; STATE OF RHODE ISLAND;
STATE OF SOUTH DAKOTA; STATE OF TEXAS;

STATE OF UTAH; STATE OF VERMONT; STATE OF WASHINGTON; STATE OF WEST VIRGINIA; STATE OF WISCONSIN; CITY AND COUNTY OF SAN FRANCISCO; PUBLIC CITIZEN; THE AMERICAN ACADEMY OF PEDIATRICS; AMERICAN CANCER SOCIETY; AMERICAN COLLEGE OF PREVENTIVE MEDICINE; AMERICAN HEART ASSOCIATION; AMERICAN LUNG ASSOCIATION; AMERICAN MEDICAL ASSOCIATION; AMERICAN MEDICAL WOMEN'S ASSOCIATION; AMERICAN PUBLIC HEALTH ASSOCIATION; AMERICAN SOCIETY OF ADDICTION MEDICINE; THE HMO GROUP; NATIONAL ASSOCIATION OF ELEMENTARY SCHOOL PRINCIPALS; NATIONAL ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS; NATIONAL CENTER FOR TOBACCO-FREE KIDS; STATE OF KENTUCKY; WASHINGTON LEGAL FOUNDATION ("WLF"); MARIO ANDRETTI; DON GARLITS; AL UNSER; RUSTY WALLACE; CALE YARBOROUGH; RICHARD BURR, CASS BALLENGER, HOWARD COBLE, UNITED STATES REPRESENTATIVES, LAUCH FAIRCLOTH, UNITED STATES SENATOR, AMICI CURIAE

No. 97-1614

NATIONAL ASSOCIATION OF CONVENIENCE STORES; ACME RETAIL, INCORPORATED, PLAINTIFFS-APPELLANTS

v.

DAVID A. KESSLER, COMMISSIONER OF THE FOOD & DRUG ADMINISTRATION; FOOD & DRUG ADMINISTRATION, DEFENDANTS-APPELLEES

ATTORNEYS GENERAL OF THE STATE OF MINNESOTA; STATE OF ALASKA; STATE OF ARIZONA;

STATE OF ARKANSAS; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF FLORIDA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF KANSAS; STATE OF MAINE; STATE OF MARYLAND; STATE OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MISSISSIPPI; STATE OF MISSOURI; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH DAKOTA; STATE OF OHIO; STATE OF OKLAHOMA; STATE OF OREGON; STATE OF RHODE ISLAND; STATE OF SOUTH DAKOTA; STATE OF TEXAS; STATE OF UTAH; STATE OF VERMONT; STATE OF WASHINGTON; STATE OF WISCONSIN; STATE OF WEST VIRGINIA; CITY AND COUNTY OF SAN FRANCISCO; PUBLIC CITIZEN; THE AMERICAN ACADEMY OF PEDIATRICS; AMERICAN CANCER SOCIETY; AMERICAN COLLEGE OF PREVENTIVE MEDICINE; AMERICAN CANCER SOCIETY; AMERICAN LUNG ASSOCIATION; AMERICAN MEDICAL ASSOCIATION; AMERICAN MEDICAL WOMEN'S ASSOCIATION; AMERICAN PUBLIC HEALTH ASSOCIATION; AMERICAN SOCIETY OF ADDICTION MEDICINE; THE HMO GROUP; NATIONAL ASSOCIATION OF ELEMENTARY SCHOOL PRINCIPALS; NATIONAL ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS; NATIONAL CENTER FOR TOBACCO-FREE KIDS; STATE OF KENTUCKY; WASHINGTON LEGAL FOUNDATION, ("WLF"); MARIO ANDRETTI, DON GARLITS; AL UNSER; RUSTY WALLACE; CALE YARBOROUGH; RICHARD BURR, CASS BALLENGER, HOWARD COBLE, UNITED STATES REPRESENTATIVES, LAUCH FAIRCLOTH, UNITED STATES SENATOR, AMICI CURIAE

No. 97-1605

UNITED STATES TOBACCO COMPANY; BROWN & WILLIAMSON TOBACCO CORPORATION; CONWOOD COMPANY, LP; NATIONAL TOBACCO COMPANY, LP; PINKERTON TOBACCO COMPANY; SWISHER INTERNATIONAL, INCORPORATED; CENTRAL CAROLINA GROCERS, INCORPORATED; J.T. DAVENPORT, INCORPORATED; NORTH CAROLINA TOBACCO DISTRIBUTORS COMMITTEE, INCORPORATED, PLAINTIFFS-APPELLANTS

v.

FOOD & DRUG ADMINISTRATION; DAVID A. KESSLER, M.D., COMMISSIONER OF FOOD AND DRUGS, DEFENDANTS-APPELLEES.
ATTORNEYS GENERAL OF THE STATE OF MINNESOTA; STATE OF ALASKA; STATE OF ARIZONA; STATE OF AR[illegible]NSAS; STATE OF COLORADO; STATE OF CON[illegible]CTICUT; STATE OF FLORIDA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF KANSAS; STATE OF MAINE; STATE OF MARYLAND; STATE OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MISSISSIPPI; STATE OF MISSOURI; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH DAKOTA; STATE OF OHIO; STATE OF OKLAHOMA; STATE OF OREGON; STATE OF PENNSYLVANIA; STATE OF RHODE ISLAND; STATE OF SOUTH DAKOTA; STATE OF TEXAS; STATE OF UTAH; STATE OF VERMONT; STATE OF WASHINGTON; STATE OF WISCONSIN; STATE OF WEST VIRGINIA; CITY AND COUNTY

OF SAN FRANCISCO; PUBLIC CITIZEN; THE AMERICAN ACADEMY OF PEDIATRICS; AMERICAN CANCER SOCIETY; AMERICAN COLLEGE OF PREVENTIVE MEDICINE; AMERICAN HEART ASSOCIATION; AMERICAN LUNG ASSOCIATION; AMERICAN MEDICAL ASSOCIATION; AMERICAN MEDICAL WOMEN'S ASSOCIATION; AMERICAN PUBLIC HEALTH ASSOCIATION; AMERICAN SOCIETY OF ADDICTION MEDICINE; THE HMO GROUP; NATIONAL ASSOCIATION OF ELEMENTARY SCHOOL PRINCIPALS; NATIONAL ASSOCIATION OF SECONDARY SCHOOL PRINCIPALS; NATIONAL CENTER FOR TOBACCO-FREE KIDS; STATE OF KENTUCKY; WASHINGTON LEGAL FOUNDATION, ("WLF"); MARIO ANDRETTI, DON GARLITS; AL UNSER; RUSTY WALLACE; CALE YARBOROUGH; RICHARD BURR, CASS BALLENGER, HOWARD COBLE, UNITED STATES REPRESENTATIVES, LAUCH FAIRCLOTH, UNITED STATES SENATOR, AMICI CURIAE

[Filed: November 10, 1998]

ORDER

On a poll of the court on the petition for rehearing en banc there voted in favor of rehearing en banc Judges Murnaghan, M. Blane Michael and Motz, and there voted against rehearing en banc Judges Widener, Ervin, Niemeyer, Luttig, Williams and Traxler.

It is accordingly ADJUDGED and ORDERED that the petition for rehearing en banc shall be, and it hereby is, denied.

The panel considered the petition for rehearing and is of opinion it is without merit.

It is accordingly ADJUDGED and ORDERED that the petition for rehearing shall be, and it hereby is, denied.

With the concurrence of Judge James H. Michael.

Judge Hall dissents. He would grant the petition for rehearing for the reasons expressed in his separate opinion filed with the opinion of the panel.

/s/ H. E. WIDENER, JR.
H.E. WIDENER, JR.
For the Court

Chief Judge WILKINSON, and Judges WILKINS, HAMILTON and KING, being disqualified, did not participate in this decision.

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APPENDIX D

21 U.S.C. 321(g)(1) provides as follows:

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

21 U.S.C. 321(h) provides as follows:

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in

vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. 353(g) provides as follows:

(1) The Secretary shall designate a component of the Food and Drug Administration to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

(A) a drug (other than a biological product), the persons charged with premarket review of drugs shall have primary jurisdiction,

(B) a device, the persons charged with premarket review of devices shall have primary jurisdiction, or

(C) a biological product, the persons charged with premarket review of biological products shall have primary jurisdiction.

21 U.S.C. 360c(a)(2) provides as follows:

(2) For purposes of this section and sections 360d and 360e of this title, the safety and effectiveness of a device are to be determined—

(A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

21 U.S.C. 360f(a) provides as follows:

(a) General rule

Whenever the Secretary finds, on the basis of all available data and information that—

(1) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury; and

(2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period;

he may initiate a proceeding to promulgate a regulation to make such device a banned device.

21 U.S.C. 360j(e) provides as follows:

(3) Restricted devices

(1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—

(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

(B) upon such other conditions as the Secretary may prescribe in such regulation,

if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. No condition prescribed under subparagraph (B) may restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device. No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board. A device subject to a regulation under this subsection is a restricted device.

(2) The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) as the Secretary may in such regulation prescribe.

21 C.F.R. Part 897 provides as follows:

Subpart A—General Provisions

§ 897.1 Scope.

(a) This part sets out the restrictions under the Federal Food, Drug, and Cosmetic Act (the act) on the sale, distribution, and use of cigarettes and smokeless tobacco that contain nicotine.

(b) The failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

§ 897.2 Purpose.

The purpose of this part is to establish restrictions on the sale, distribution, and use of cigarettes and smokeless tobacco in order to reduce the number of children and adolescents who use these products, and to reduce the life-threatening consequences associated with tobacco use.

§ 897.3 Definitions.

(a) *Cigarette* means any product which contains nicotine, is intended to be burned under ordinary conditions of use, and consists of:

(1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; or

(2) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (a)(1) of this section.

(b) *Cigarette tobacco* means any product that consists of loose tobacco that contains or delivers nicotine and is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements pertaining to cigarettes shall also apply to cigarette tobacco.

(c) *Distributor* means any person who furthers the distribution of cigarettes or smokeless tobacco, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

(d) *Manufacturer* means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette or smokeless tobacco product.

(e) *Nicotine* means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl)pyridine or $C_{10}H_{14}N_2$, including any salt or complex of nicotine.

(f) *Package* means a pack, box, carton, or container of any kind in which cigarettes or smokeless tobacco are

offered for sale, sold, or otherwise distributed to consumers.

(g) *Point of sale* means any location at which a consumer can purchase or otherwise obtain cigarettes or smokeless tobacco for personal consumption.

(h) *Retailer* means any person who sells cigarettes or smokeless tobacco to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under this part.

(i) *Smokeless tobacco* means any product that consists of cut, ground, powdered, or leaf tobacco that contains nicotine and that is intended to be placed in the oral cavity.

Subpart B—Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age

§ 897.10 General responsibilities of manufacturers, distributors, and retailers.

Each manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes or smokeless tobacco it manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale comply with all applicable requirements under this part.

§ 897.12 Additional responsibilities of manufacturers.

In addition to the other responsibilities under this part, each manufacturer shall remove from each point of sale all self-service displays, advertising, labeling,

and other items that the manufacturer owns that do not comply with the requirements under this part.

§ 897.14 Additional responsibilities of retailers.

In addition to the other requirements under this part, each retailer is responsible for ensuring that all sales of cigarettes or smokeless tobacco to any person comply with the following requirements:

(a) No retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age;

(b)(1) Except as otherwise provided in § 897.16(c)(2)(i) and in paragraph (b)(2) of this section, each retailer shall verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age;

(2) No such verification is required for any person over the age of 26;

(c) Except as otherwise provided in § 897.16(c)(2)(ii), a retailer may sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine);

(d) No retailer may break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size defined in § 897.16(b), or any quantity of cigarette tobacco or smokeless

tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use; and

(e) Each retailer shall ensure that all self-service displays, advertising, labeling, and other items, that are located in the retailer's establishment and that do not comply with the requirements of this part, are removed or are brought into compliance with the requirements under this part.

§ 897.16 Conditions of manufacture, sale, and distribution.

(a) *Restriction on product names.* A manufacturer shall not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for a tobacco product whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995.

(b) *Minimum cigarette package size.* Except as otherwise provided under this section, no manufacturer, distributor, or retailer may sell or cause to be sold, or distribute or cause to be distributed, any cigarette package that contains fewer than 20 cigarettes.

(c) *Vending machines, self-service displays, mail-order sales, and other "impersonal" modes of sale.* (1) Except as otherwise provided under this section, a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. Examples of methods of sale that

are not permitted include vending machines and self-service displays.

(2) Exceptions. The following methods of sale are permitted:

(i) Mail-order sales, excluding mail-order redemption of coupons and distribution of free samples through the mail; and

(ii) Vending machines (including vending machines that sell packaged, single cigarettes) and self-service displays that are located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.

(d) *Free samples.* No manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes or smokeless tobacco.

(e) *Restrictions on labels, labeling, and advertising.* No manufacturer, distributor, or retailer may sell or distribute, or cause to be sold or distributed, cigarettes or smokeless tobacco with labels, labeling, or advertising not in compliance with subparts C and D of this part, and other applicable requirements.

Subpart C—Labels

§ 897.24 Established names for cigarettes and smokeless tobacco.

Each cigarette or smokeless tobacco package shall bear, as provided in section 502 of the act, the following established name: "Cigarettes", "Cigarette Tobacco", "Loose Leaf Chewing Tobacco", "Plug Chewing Tobacco", "Twist Chewing Tobacco", "Moist Snuff", or "Dry Snuff", whichever name is appropriate.

§ 897.25 Statement of intended use and age restriction.

Each cigarette or smokeless tobacco package, that is offered for sale, sold, or otherwise distributed shall bear the following statement: "Nicotine-Delivery Device for Persons 18 or Older".

Subpart D—Labeling and Advertising

§ 897.30 Scope of permissible forms of labeling and advertising.

(a)(1) A manufacturer, distributor, or retailer may, in accordance with this subpart D, disseminate or cause to be disseminated advertising or labeling which bears a cigarette or smokeless tobacco brand name (alone or in conjunction with any other word) or any other indicia of tobacco product identification, in newspapers; in magazines; in periodicals or other publications (whether periodic or limited distribution); on billboards, posters, and placards; in nonpoint-of-sale promotional material (including direct mail); in point-of-sale promotional

material; and in audio or video formats delivered at a point-of-sale.

(2) A manufacturer, distributor, or retailer intending to disseminate, or to cause to be disseminated, advertising or labeling for cigarettes or smokeless tobacco in a medium that is not listed in paragraph (a)(1) of this section, shall notify the agency 30 days prior to the use of such medium. The notice shall describe the medium and discuss the extent to which the advertising or labeling may be seen by persons younger than 18 years of age. The manufacturer, distributor, or retailer shall send this notice to the Division of Drug Marketing, Advertising, and Communications, 5600 Fishers Lane (HFD-40), rm. 17B-20, Rockville, MD 20857.

(b) No outdoor advertising for cigarettes or smokeless tobacco, including billboards, posters, or placards, may be placed within 1,000 feet of the perimeter of any public playground or playground area in a public park (e.g., a public park with equipment such as swings and seesaws, baseball diamonds, or basketball courts), elementary school, or secondary school.

(c) This subpart D does not apply to cigarette or smokeless tobacco package labels.

§ 897.32 Format and content requirements for labeling and advertising.

(a) Except as provided in paragraph (b) of this section, each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, any labeling or

advertising for cigarettes or smokeless tobacco shall use only black text on a white background. This section does not apply to advertising:

(1) In any facility where vending machines and self-service displays are permitted under this part, provided that the advertising is not visible from outside the facility and that it is affixed to a wall or fixture in the facility; or

(2) Appearing in any publication (whether periodic or limited distribution) that the manufacturer, distributor, or retailer demonstrates is an adult publication. For the purposes of this section, an adult publication is a newspaper, magazine, periodical, or other publication:

(i) Whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence; and

(ii) That is read by fewer than 2 million persons younger than 18 years of age as measured by competent and reliable survey evidence.

(b) Labeling and advertising in an audio or video format shall be limited as follows:

(1) Audio format shall be limited to words only with no music or sound effects.

(2) Video formats shall be limited to static black text only on a white background. Any audio with the video shall be limited to words only with no music or sound effects.

(c) Each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, advertising permitted under this subpart D, shall include, as provided in section 502 of the act, the product's established name and a statement of its intended use as follows: "Cigarettes—A Nicotine-Delivery Device for Persons 18 or Older", "Cigarette Tobacco—A Nicotine-Delivery Device for Persons 18 or Older", or "Loose Leaf Chewing Tobacco", "Plug Chewing Tobacco", "Twist Chewing Tobacco", "Moist Snuff" or "Dry Snuff", whichever is appropriate for the product, followed by the words "A Nicotine-Delivery Device for Persons 18 or Older".

§ 897.34 Sale and distribution of nontobacco items and services, gifts, and sponsorship of events.

(a) No manufacturer and no distributor of imported cigarettes or smokeless tobacco may market, license, distribute, sell, or cause to be marketed, licensed, distributed, or sold any item (other than cigarettes or smokeless tobacco) or service, which bears the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

(b) No manufacturer, distributor, or retailer may offer or cause to be offered any gift or item (other then cigarettes or smokeless tobacco) to any person purchasing cigarettes or smokeless tobacco in consideration of the purchase thereof, or to any person in

consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase.

(c) No manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco. Nothing in this paragraph prevents a manufacturer, distributor, or retailer from sponsoring or causing to be sponsored any athletic, musical, artistic, or other social or cultural event, or team or entry, in the name of the corporation which manufactures the tobacco product, provided that both the corporate name and the corporation were registered and in use in the United States prior to January 1, 1995, and that the corporate name does not include any brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.